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(54) **LOCKING COMPONENT FOR AN EMBOLIC FILTER ASSEMBLY**

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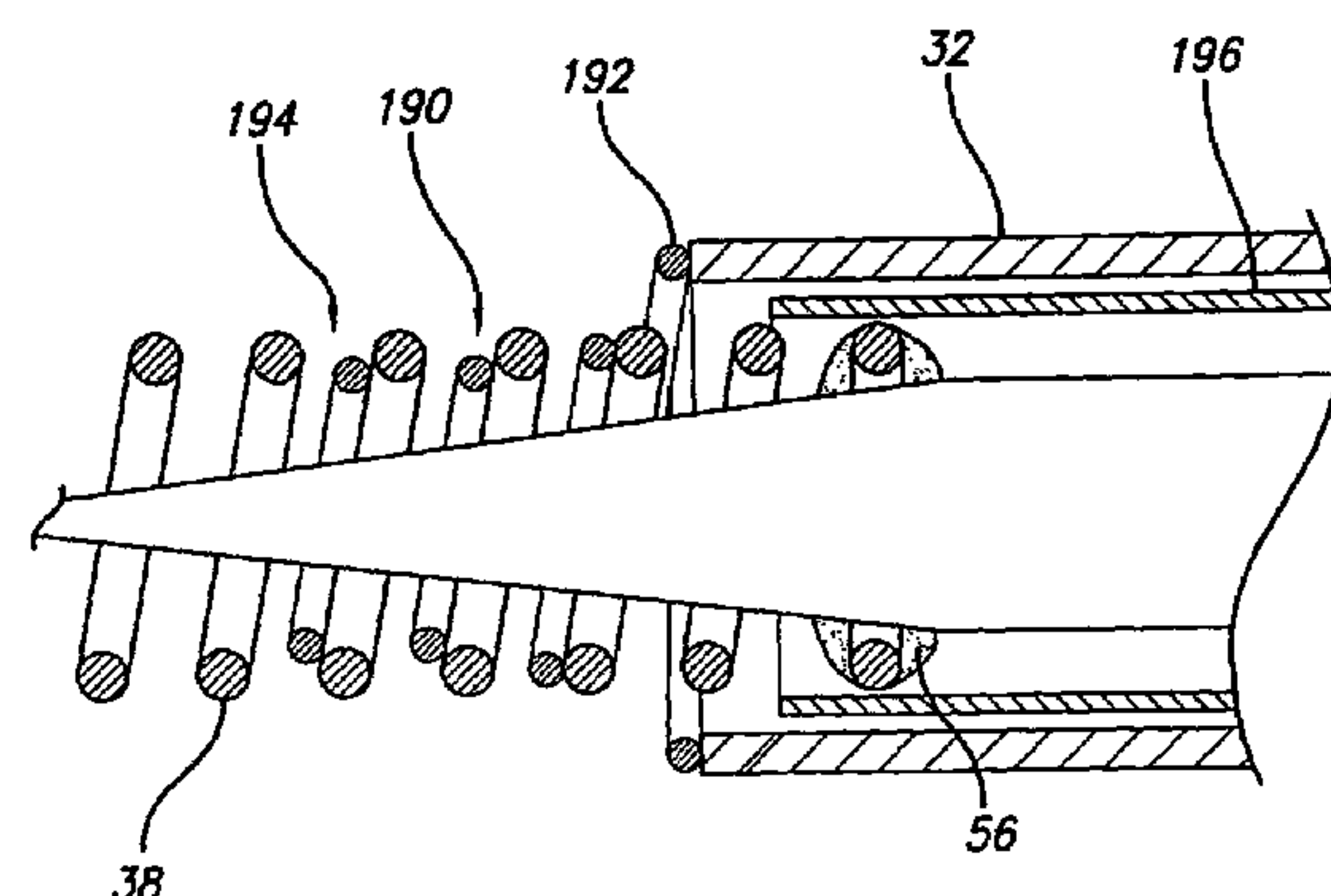
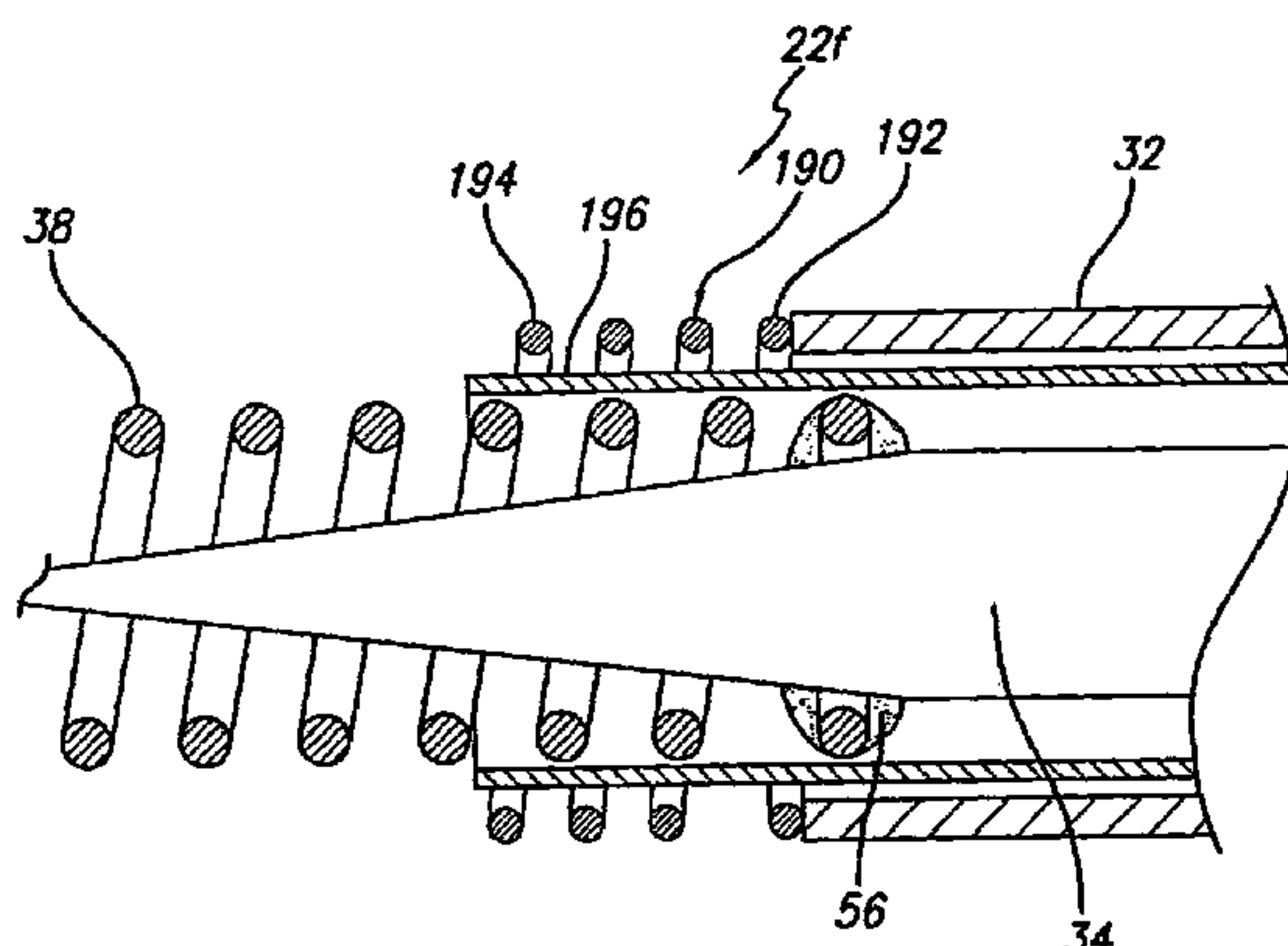
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(57) **ABSTRACT**

A locking component for locking a medical device onto a guide wire. Such medical devices include, for example, an embolic filter assembly used to capture embolic material that may be created and released into a patient's vasculature during a stenting or angioplasty procedure. The embolic filter assembly tracks along the guide wire, and is delivered to a treatment site where it is locked in place and deployed. The locking component enables the filter assembly to lock onto any standard guide wire, and does not require a modified guide wire that has a specially-designed fitting or stop to accomplish the locking function.

12 Claims, 10 Drawing Sheets



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FIG. 1

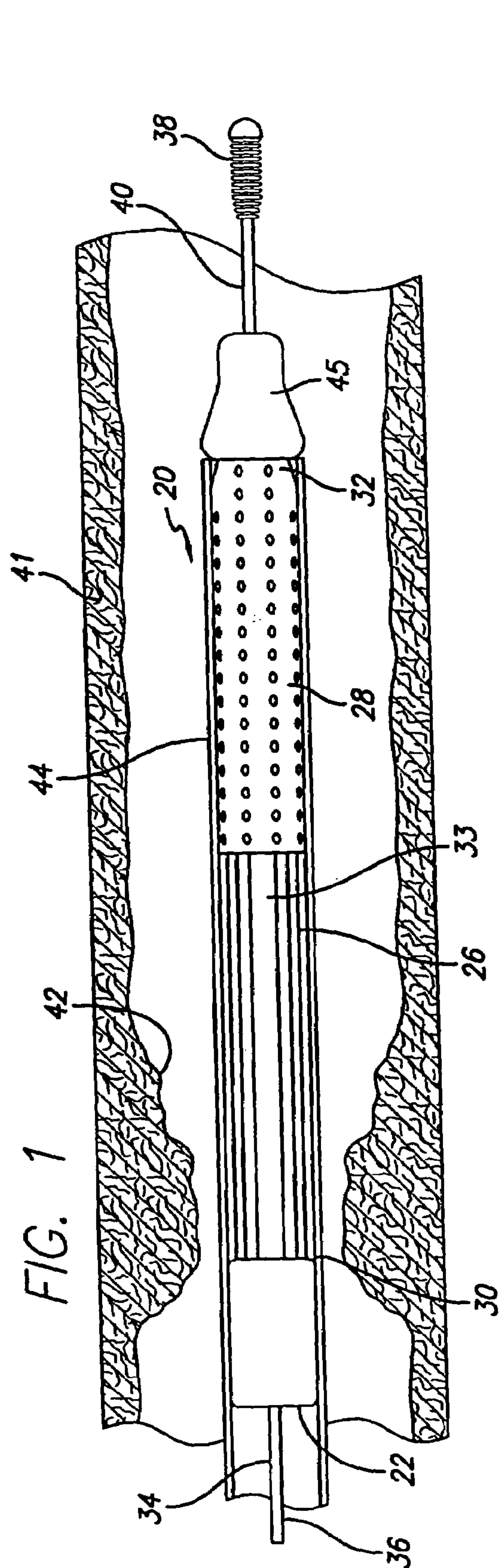
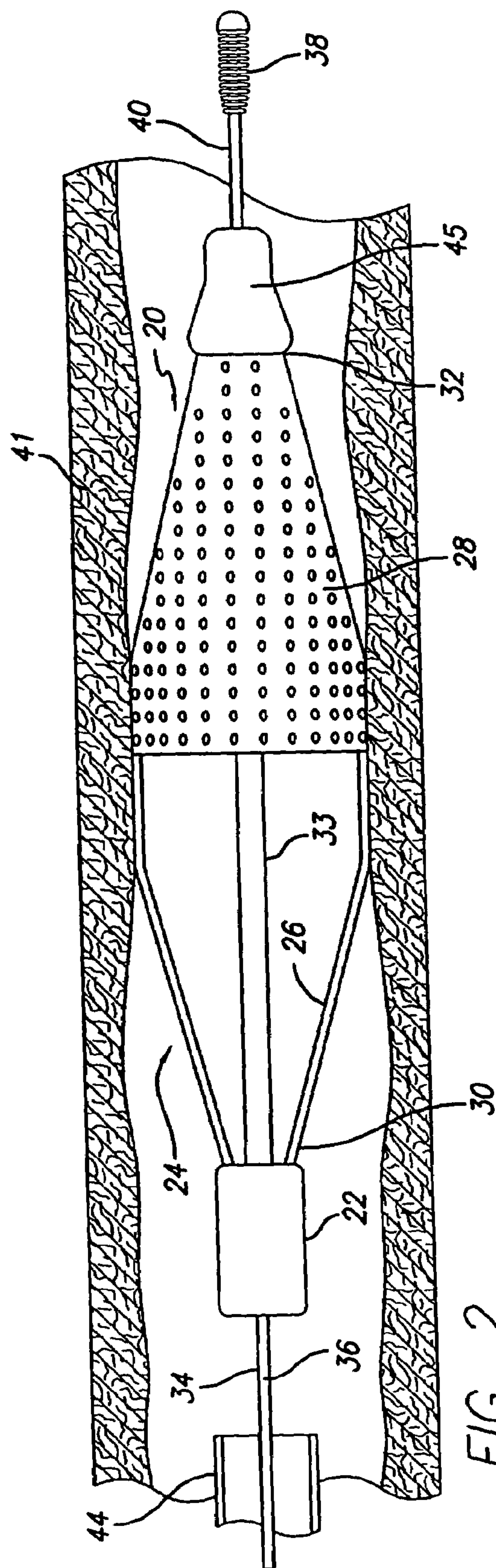
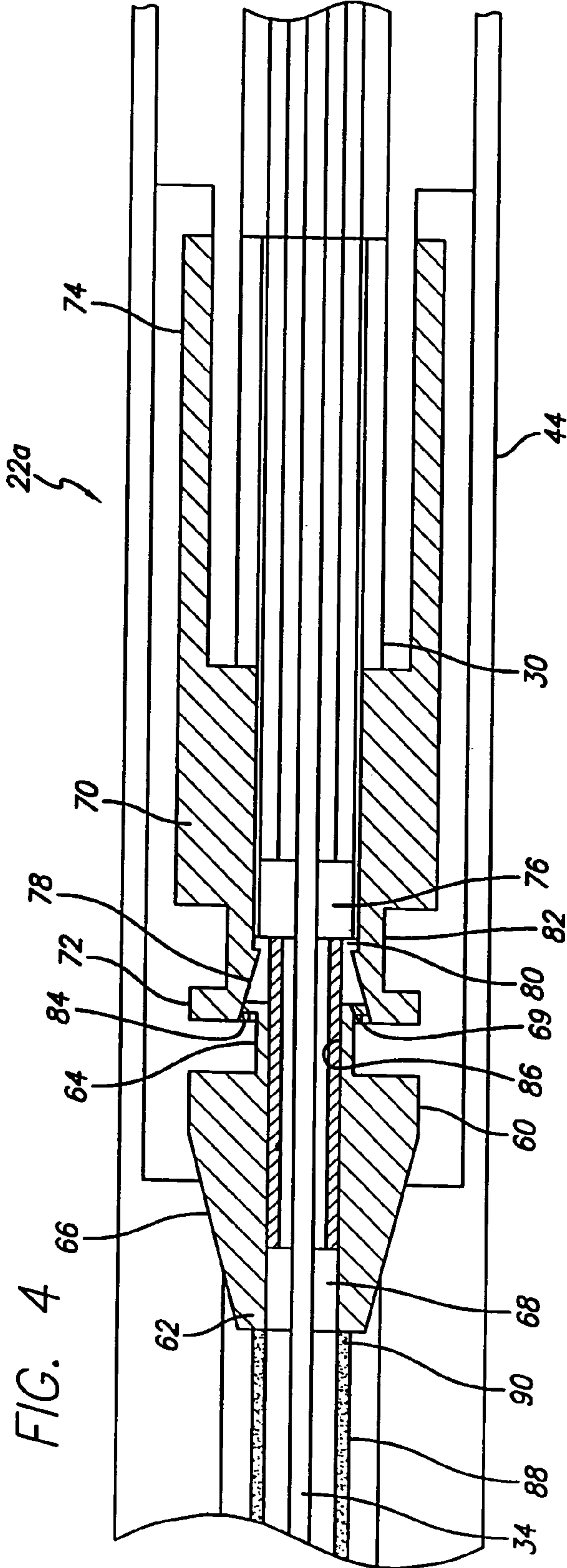
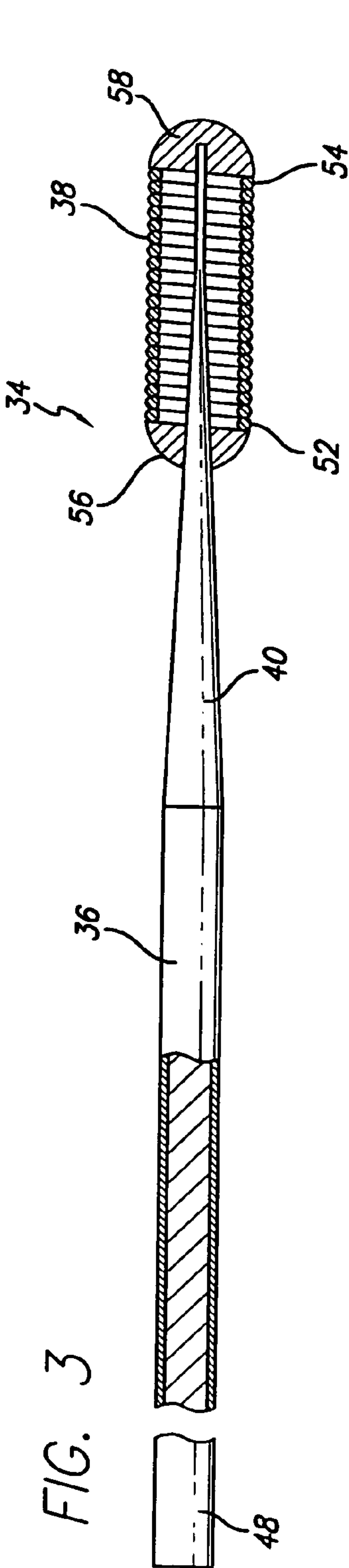
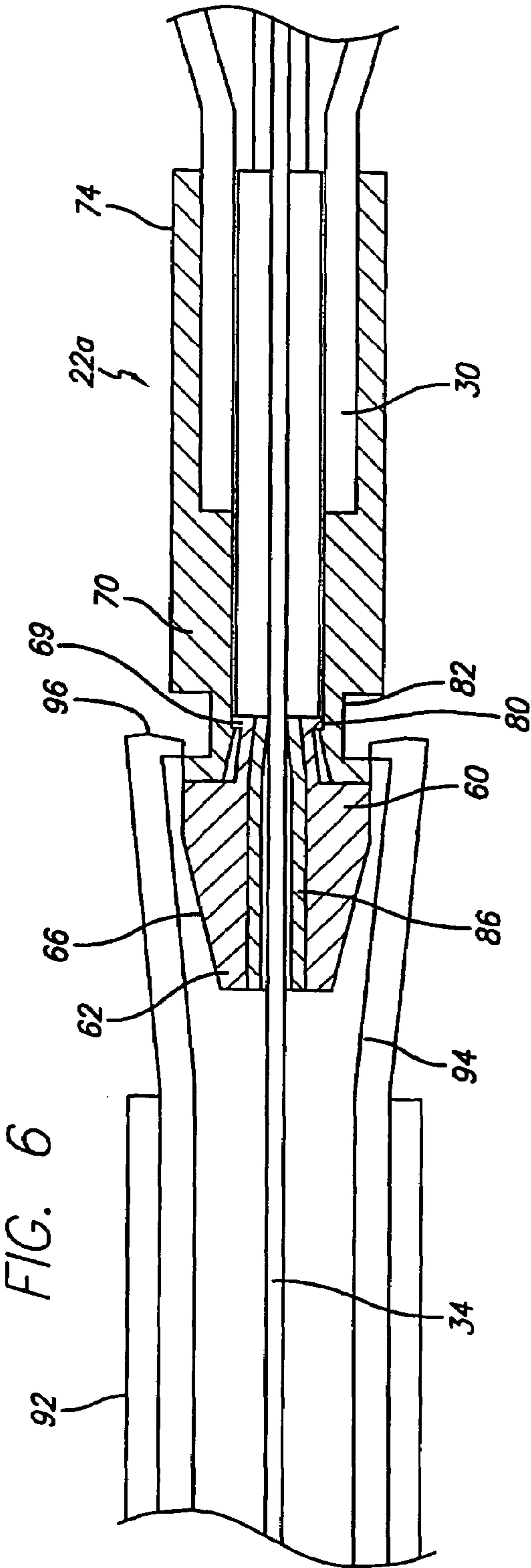
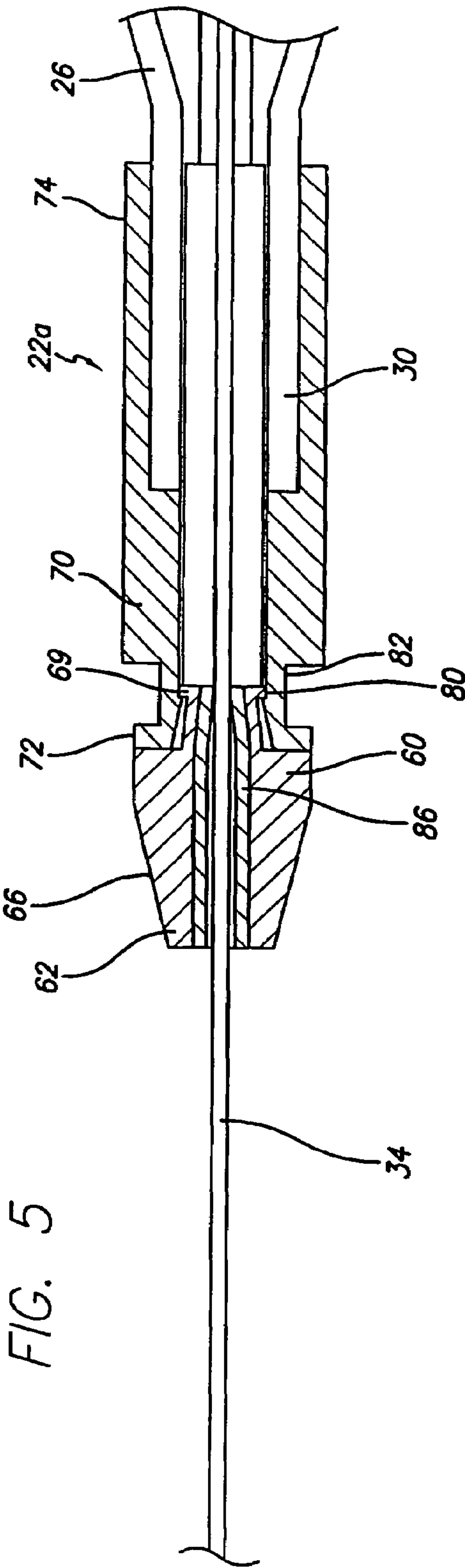
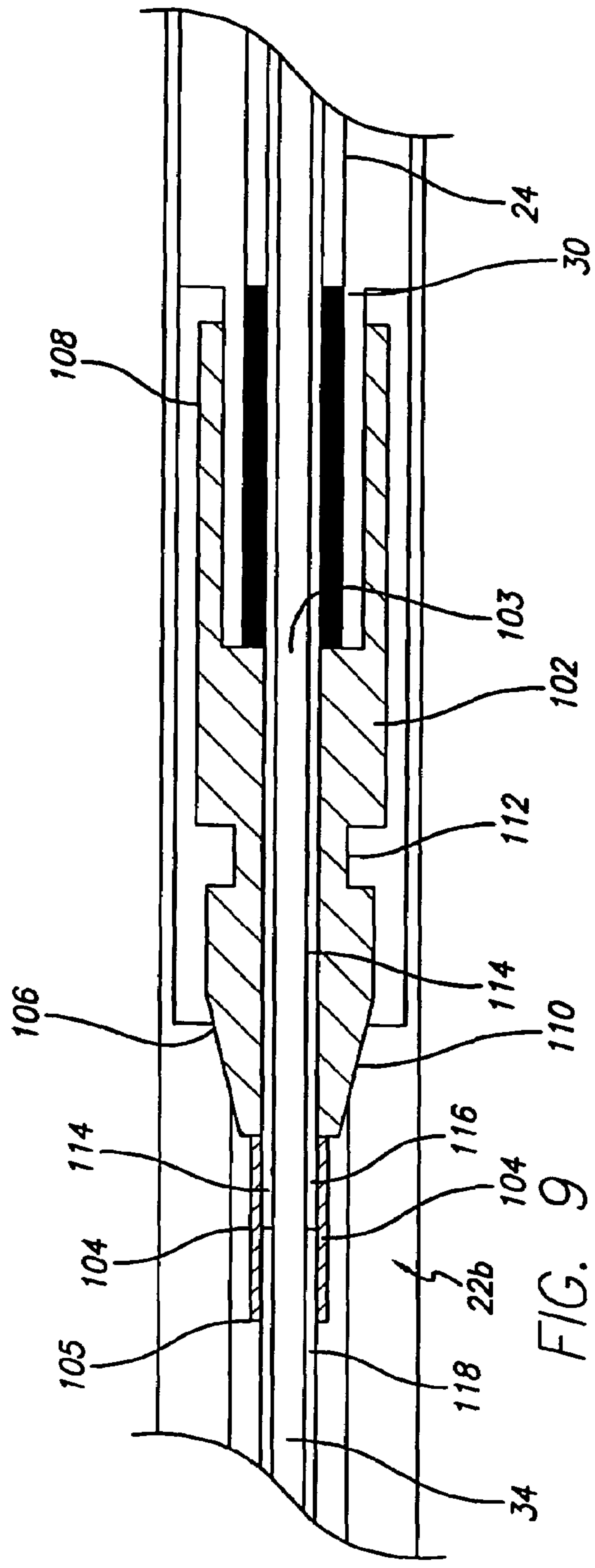
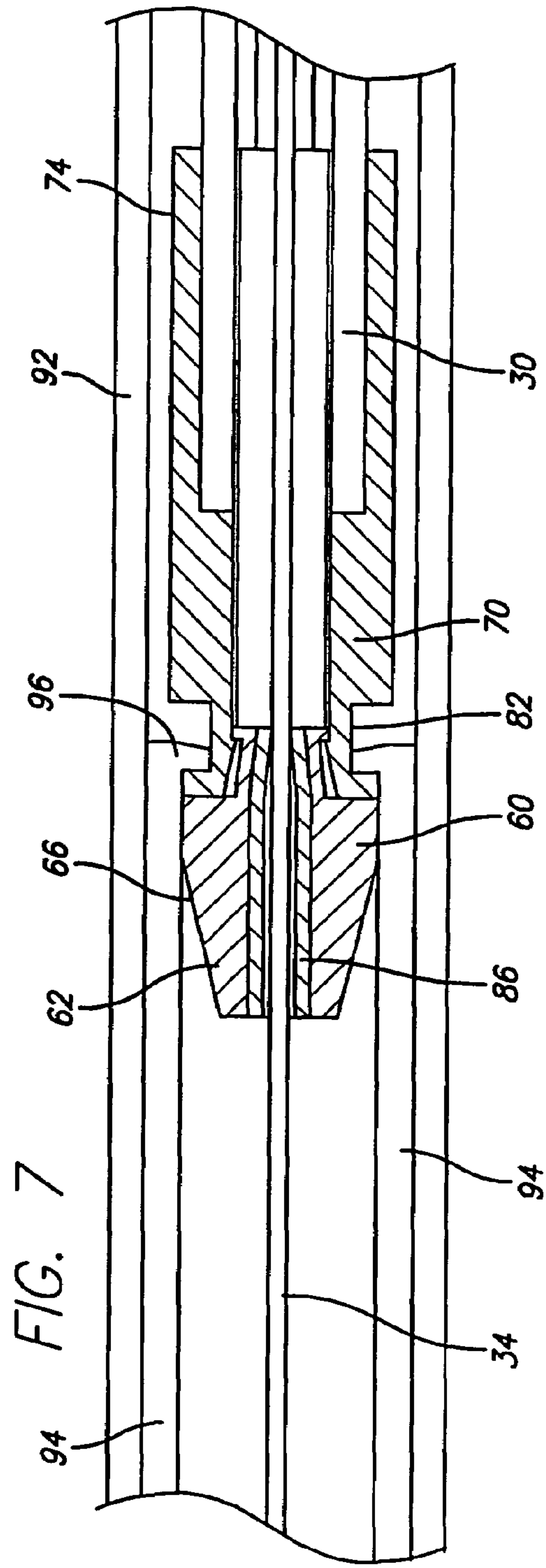


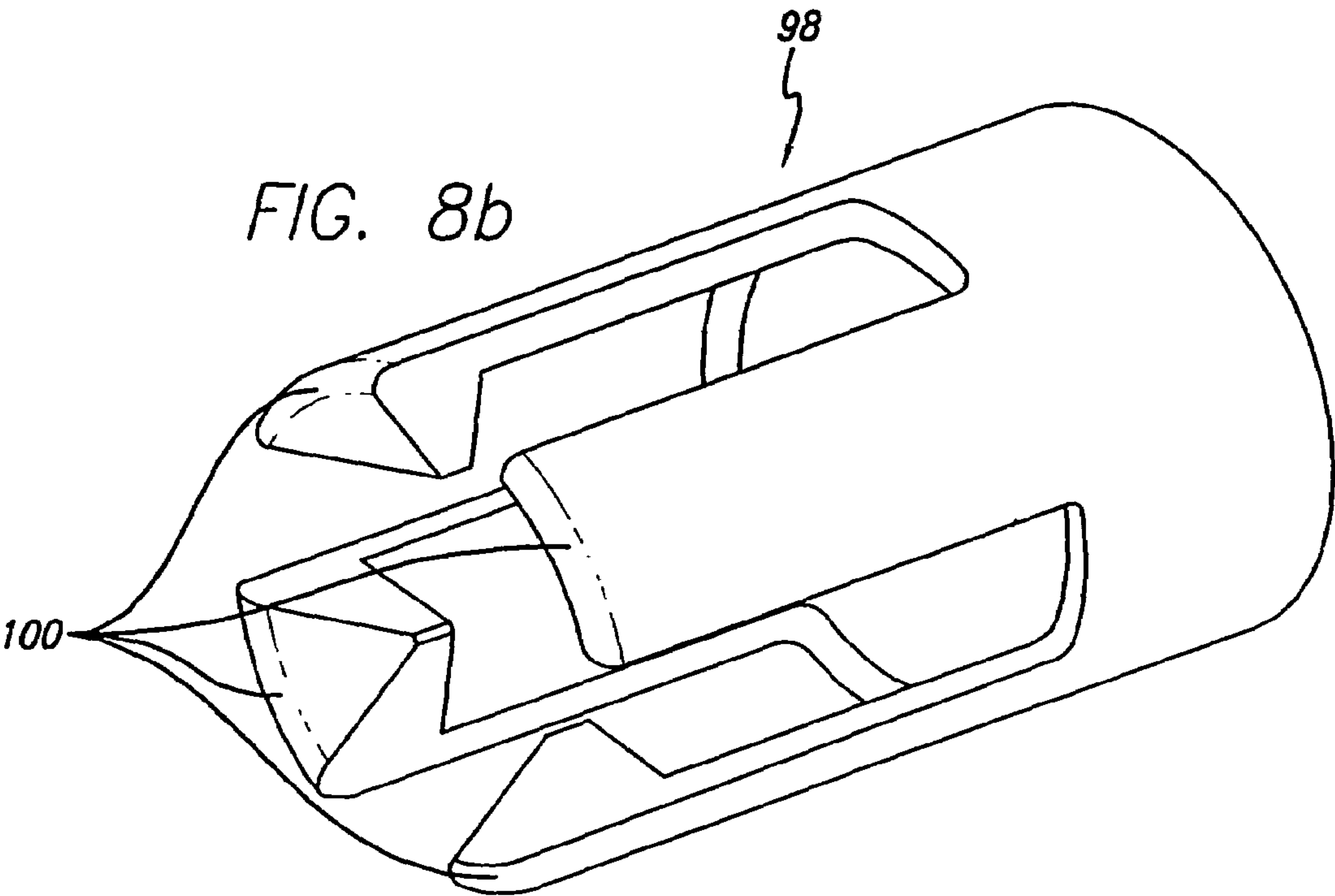
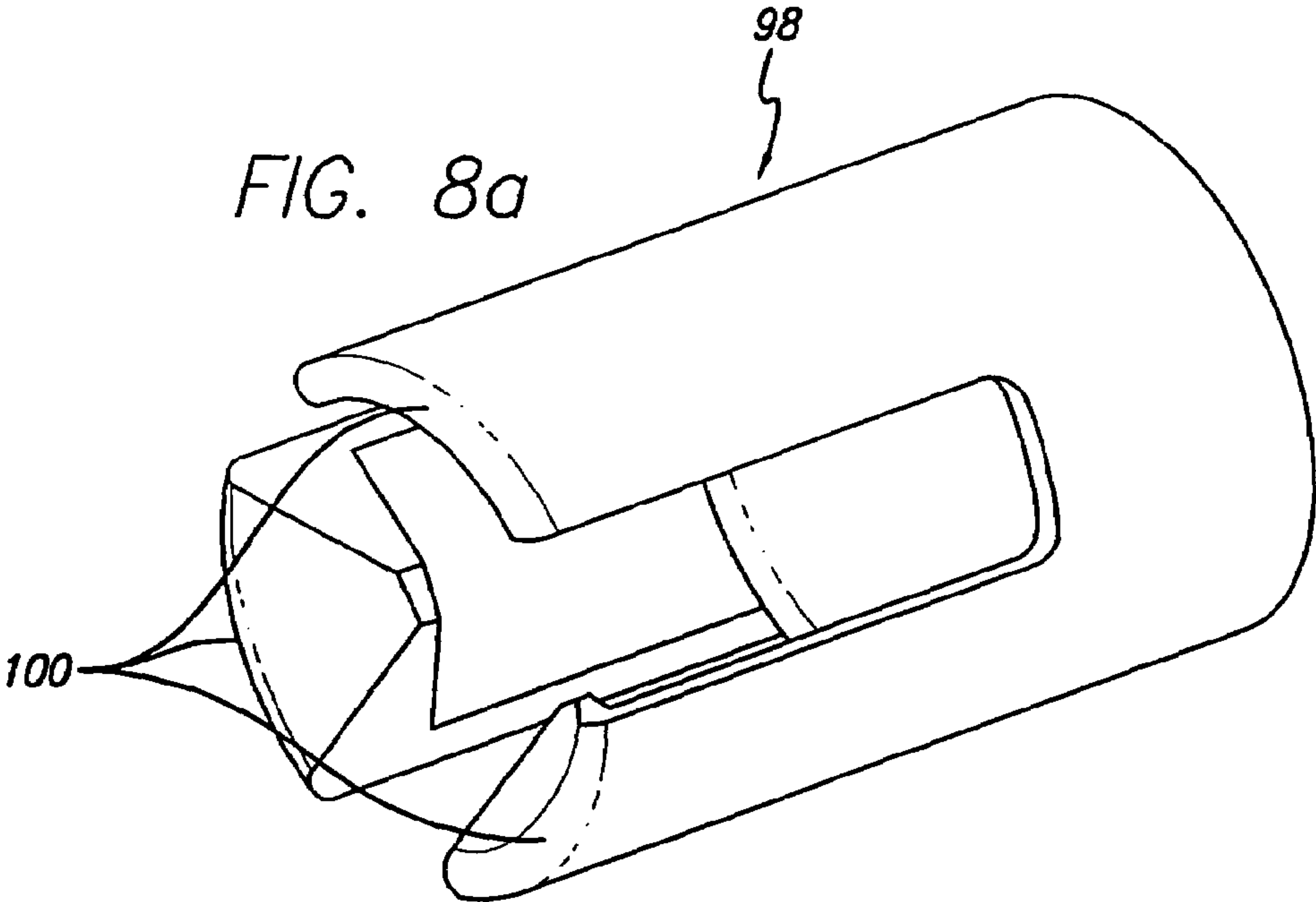
FIG. 2

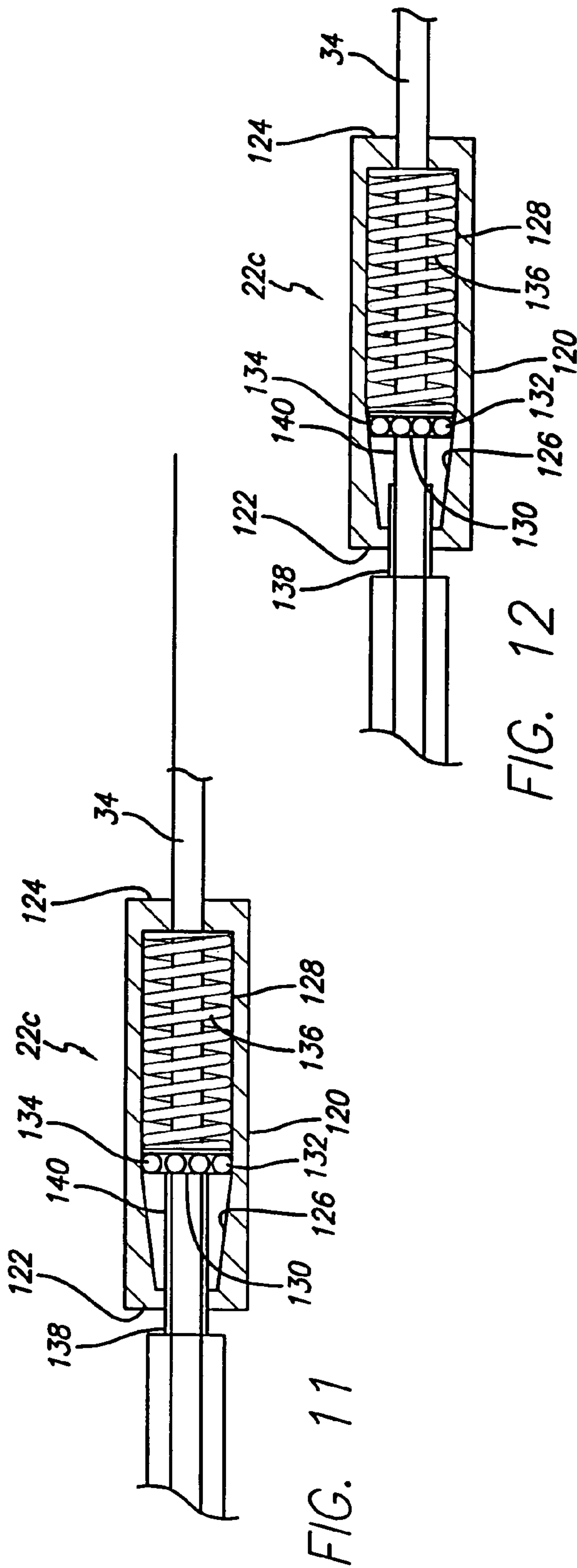
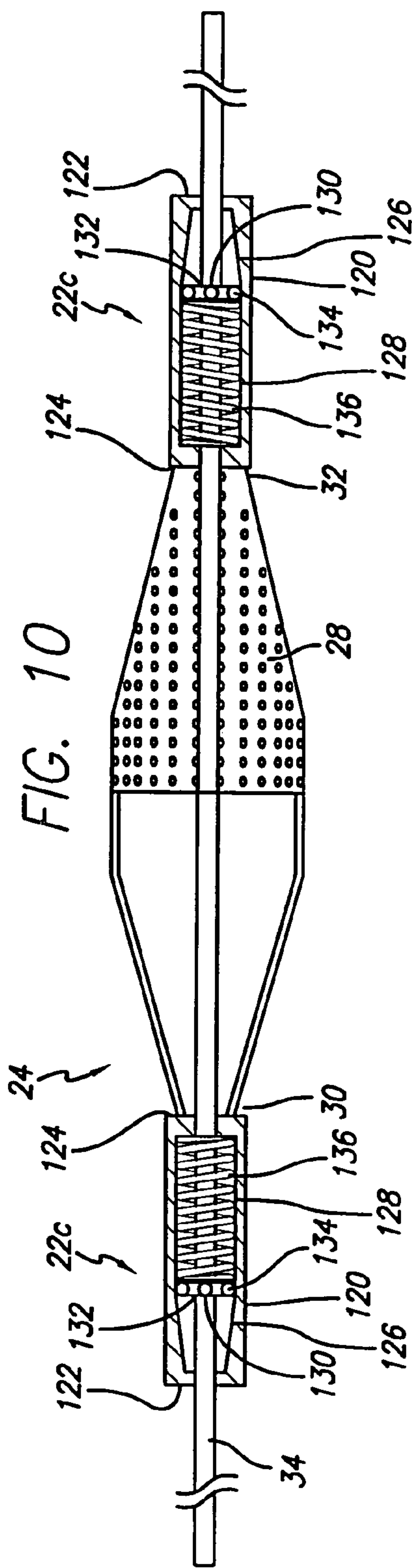


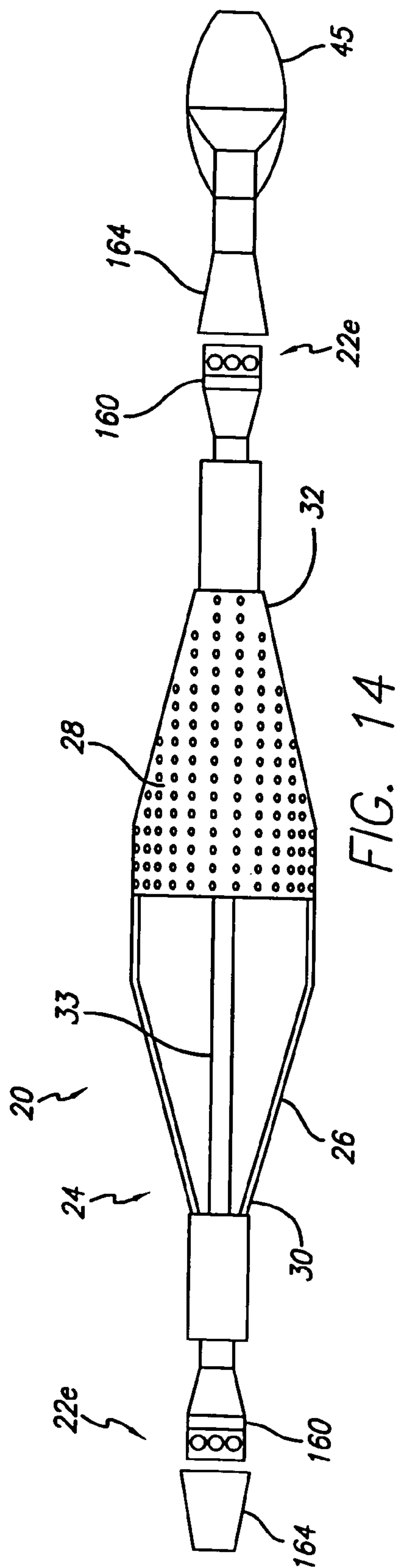
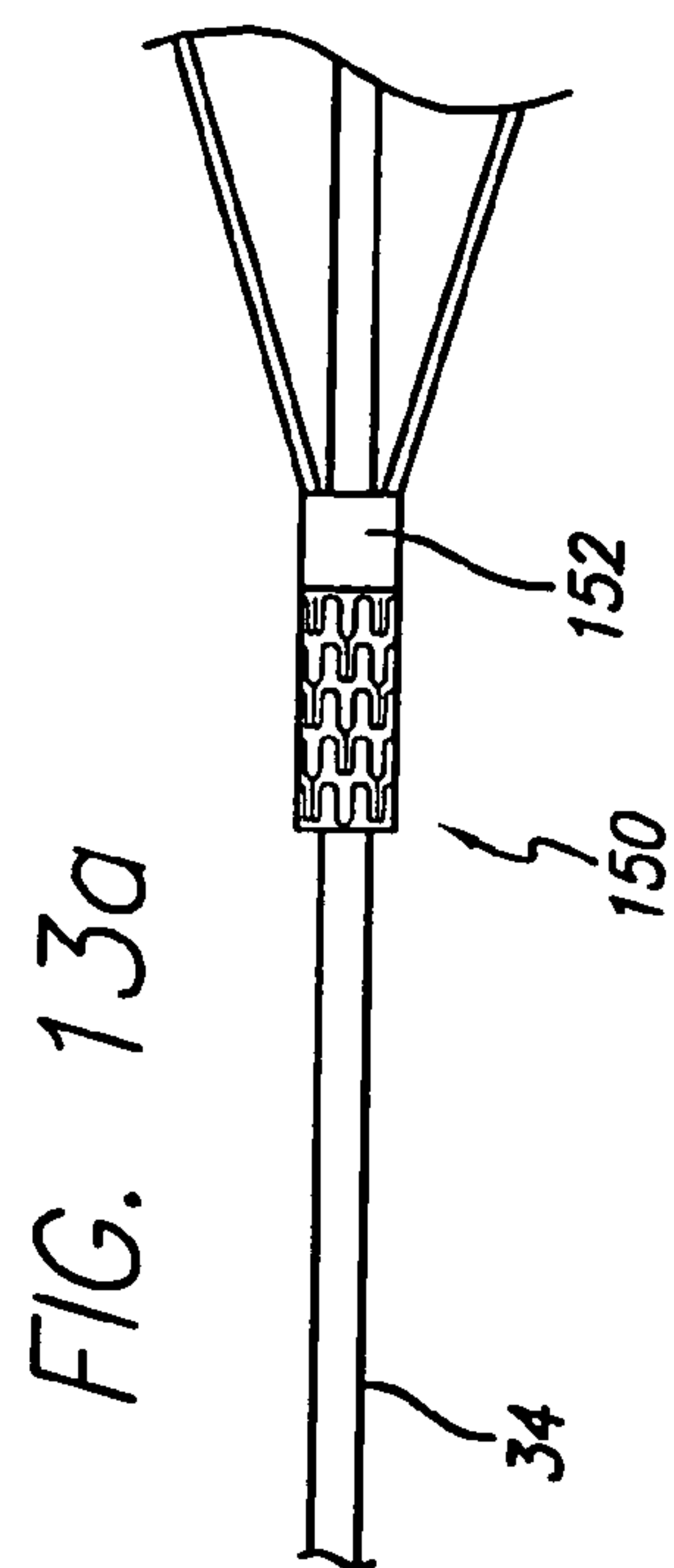
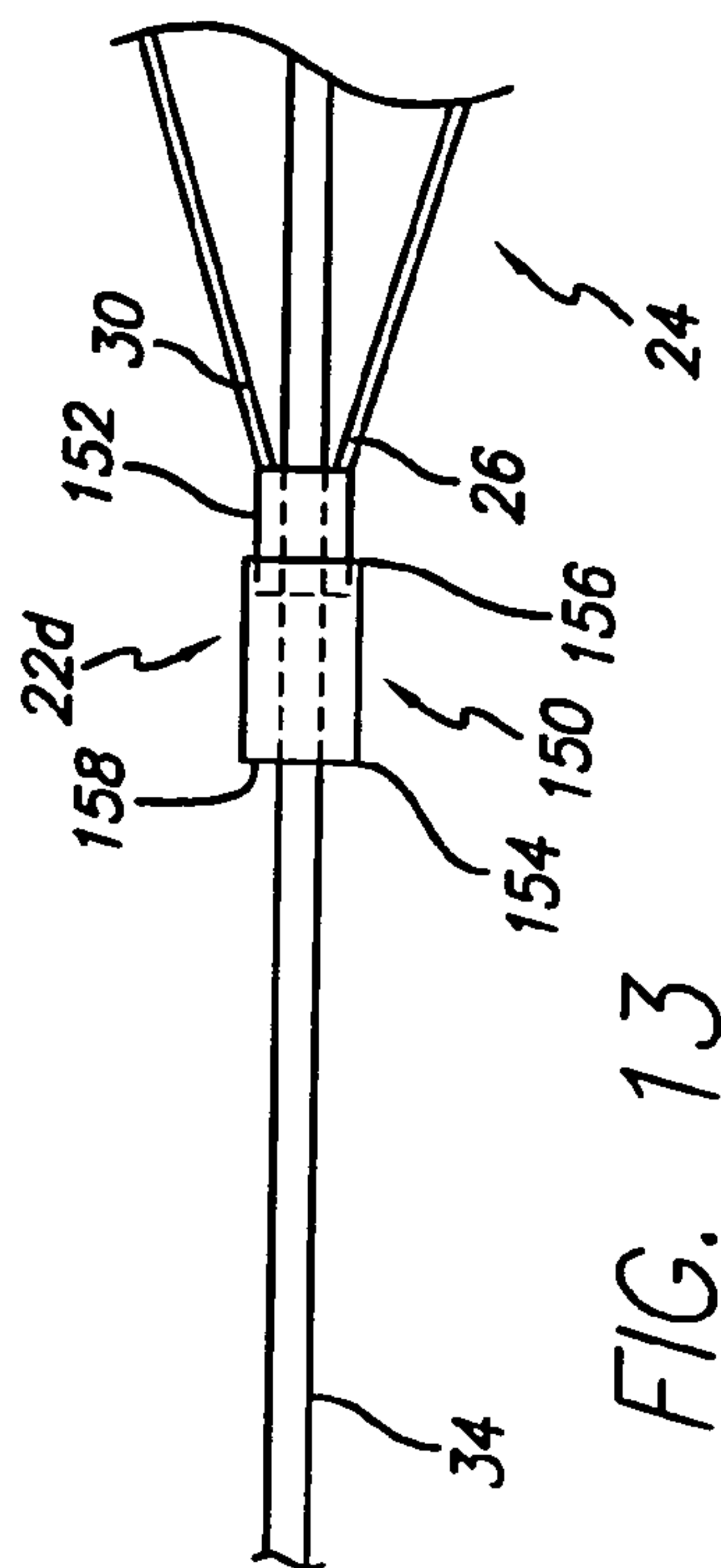












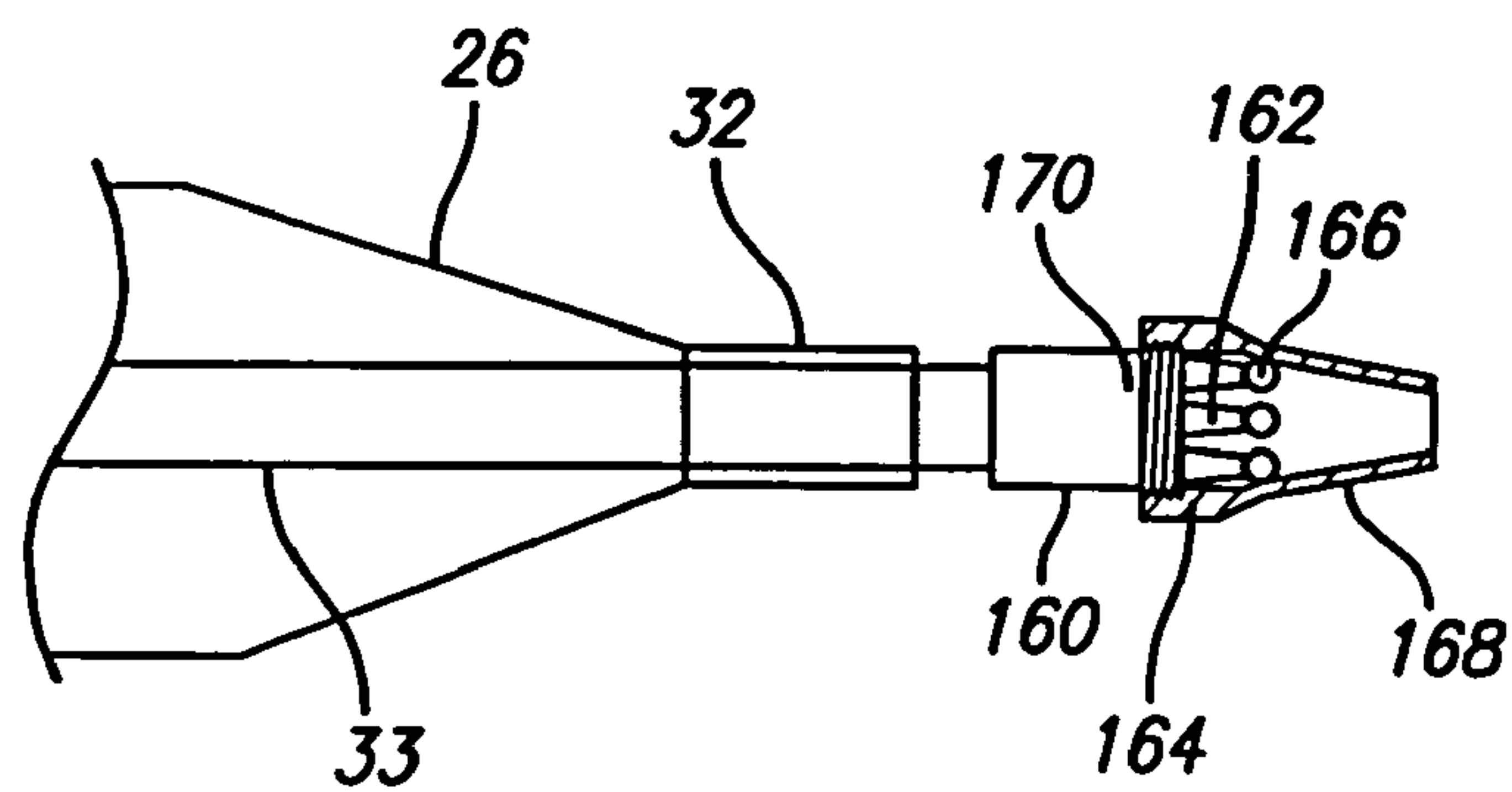


FIG. 15

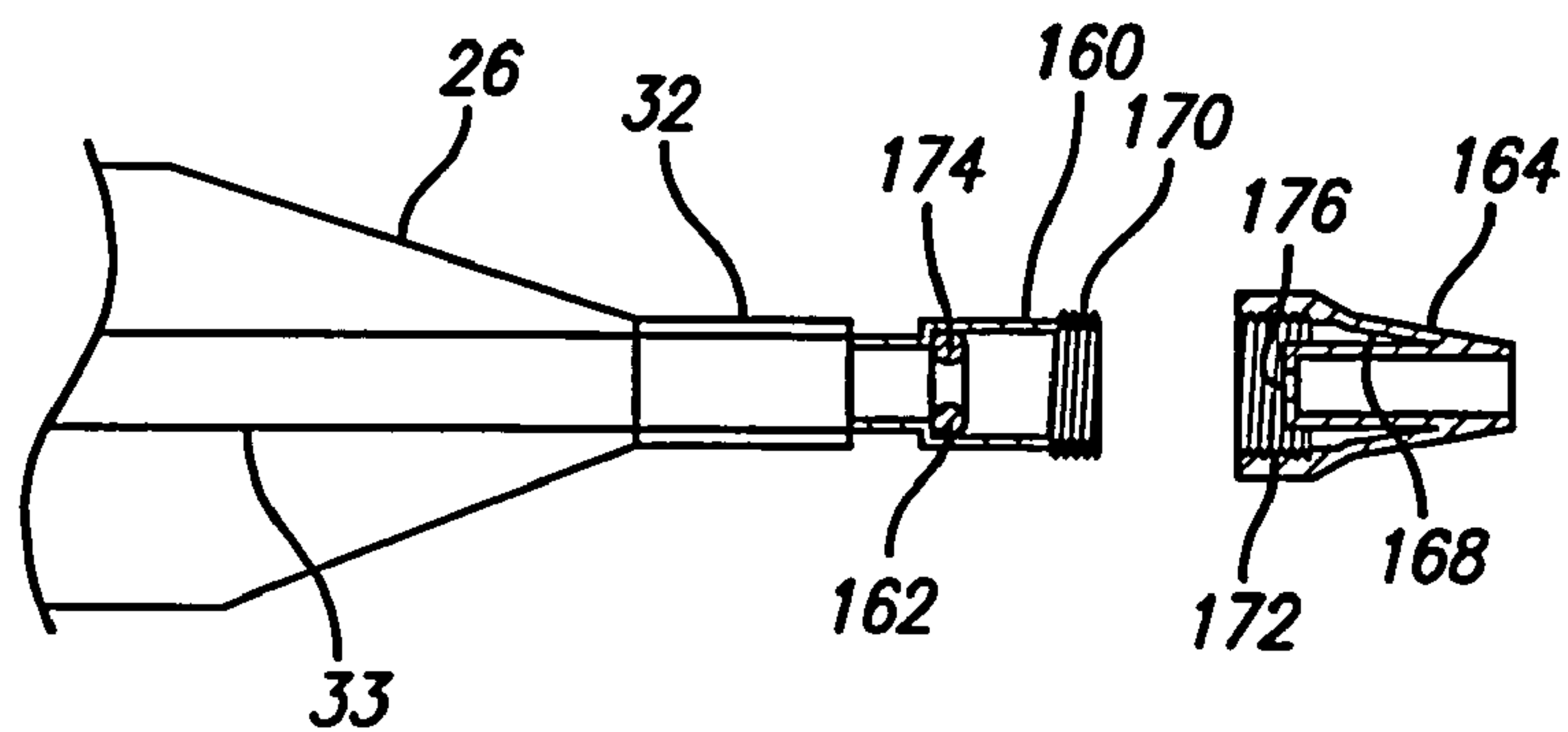


FIG. 16

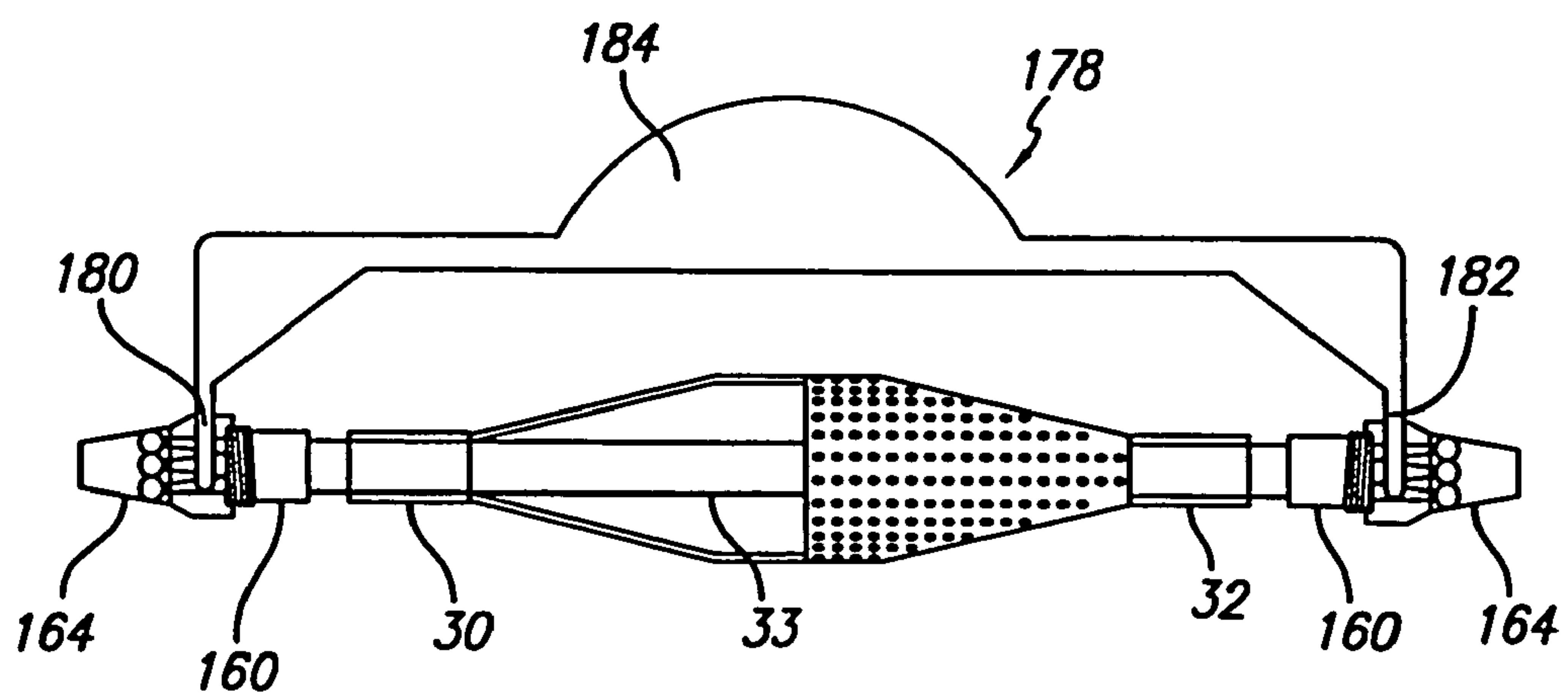


FIG. 17

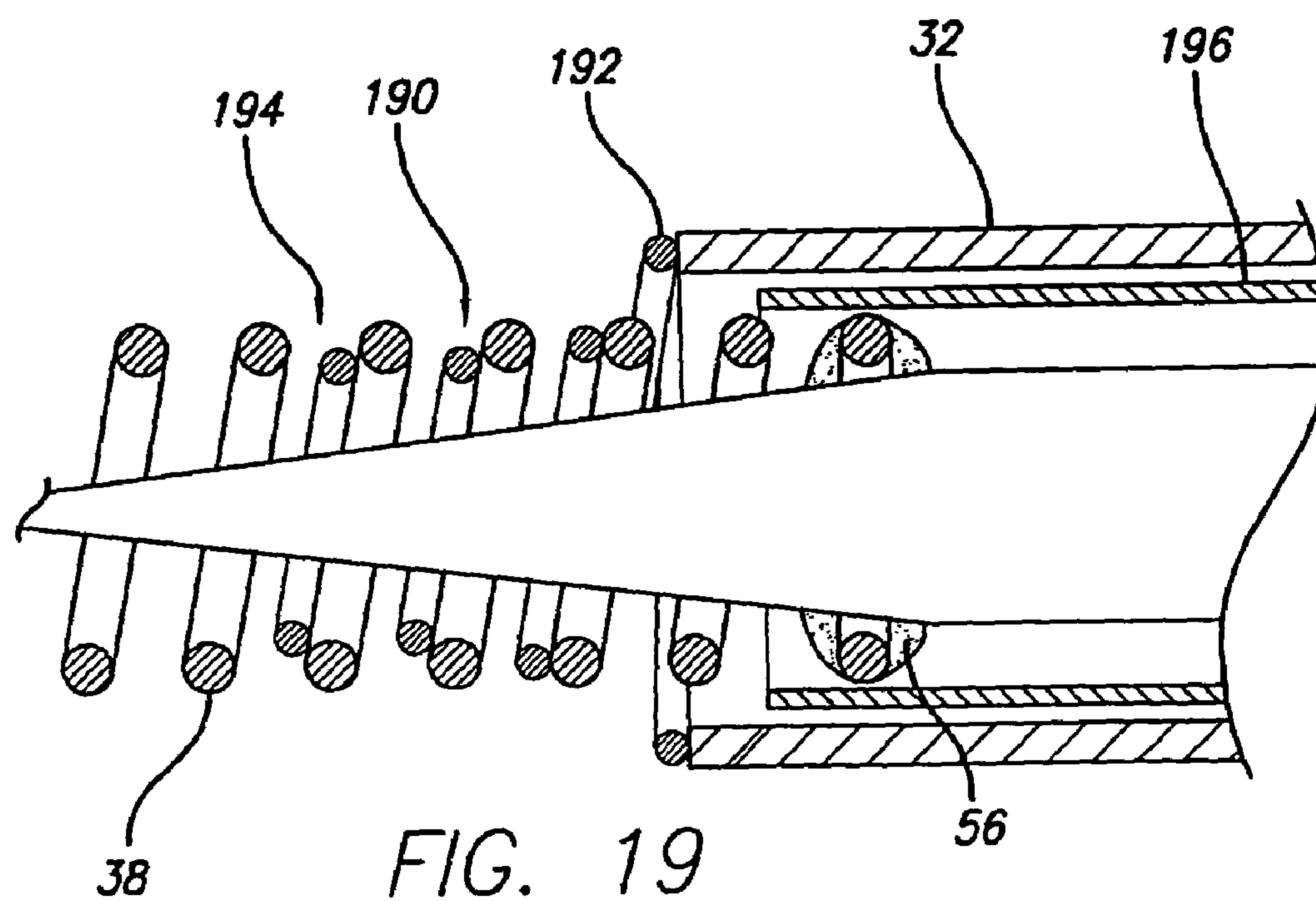
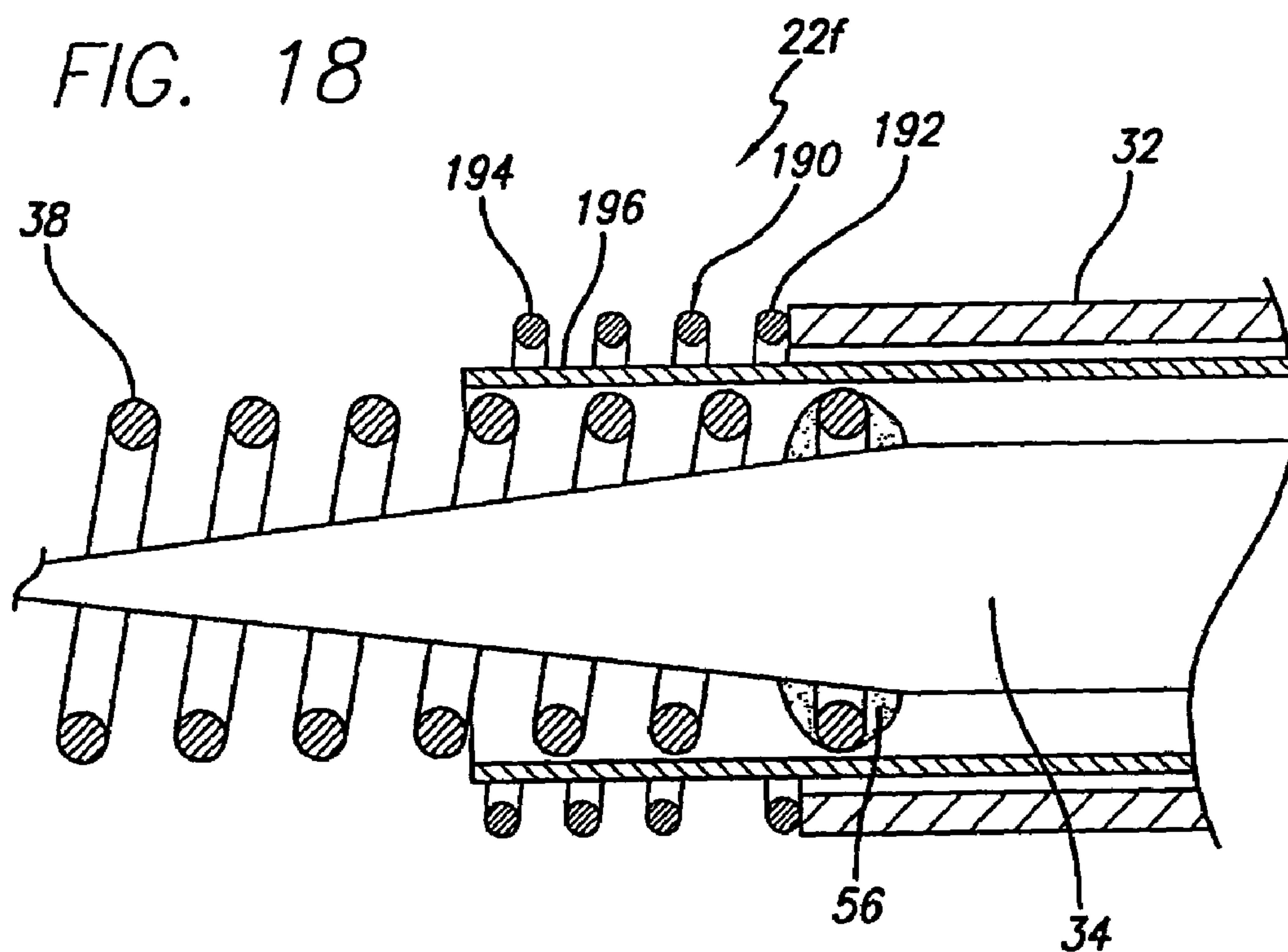


FIG. 20

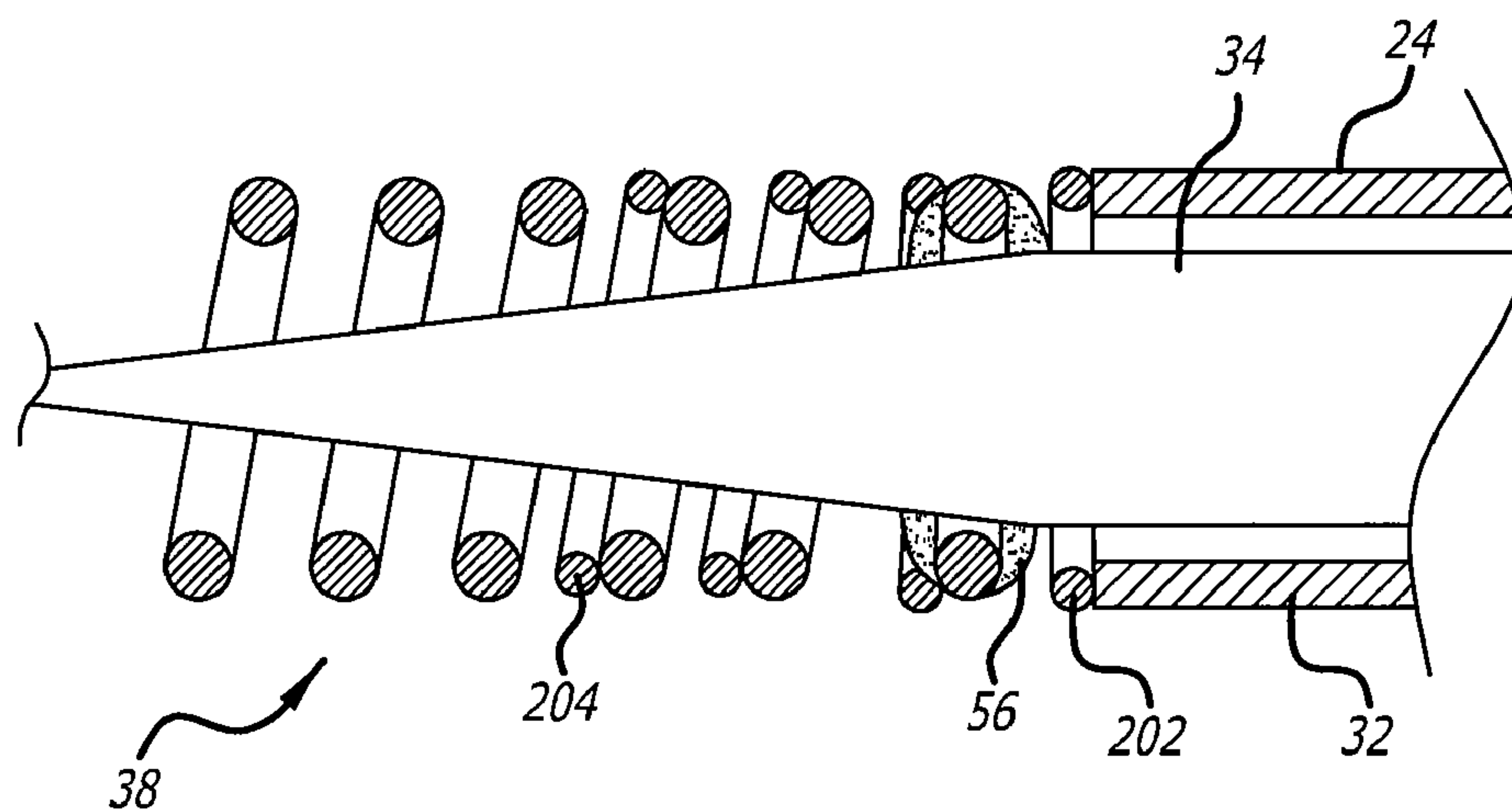
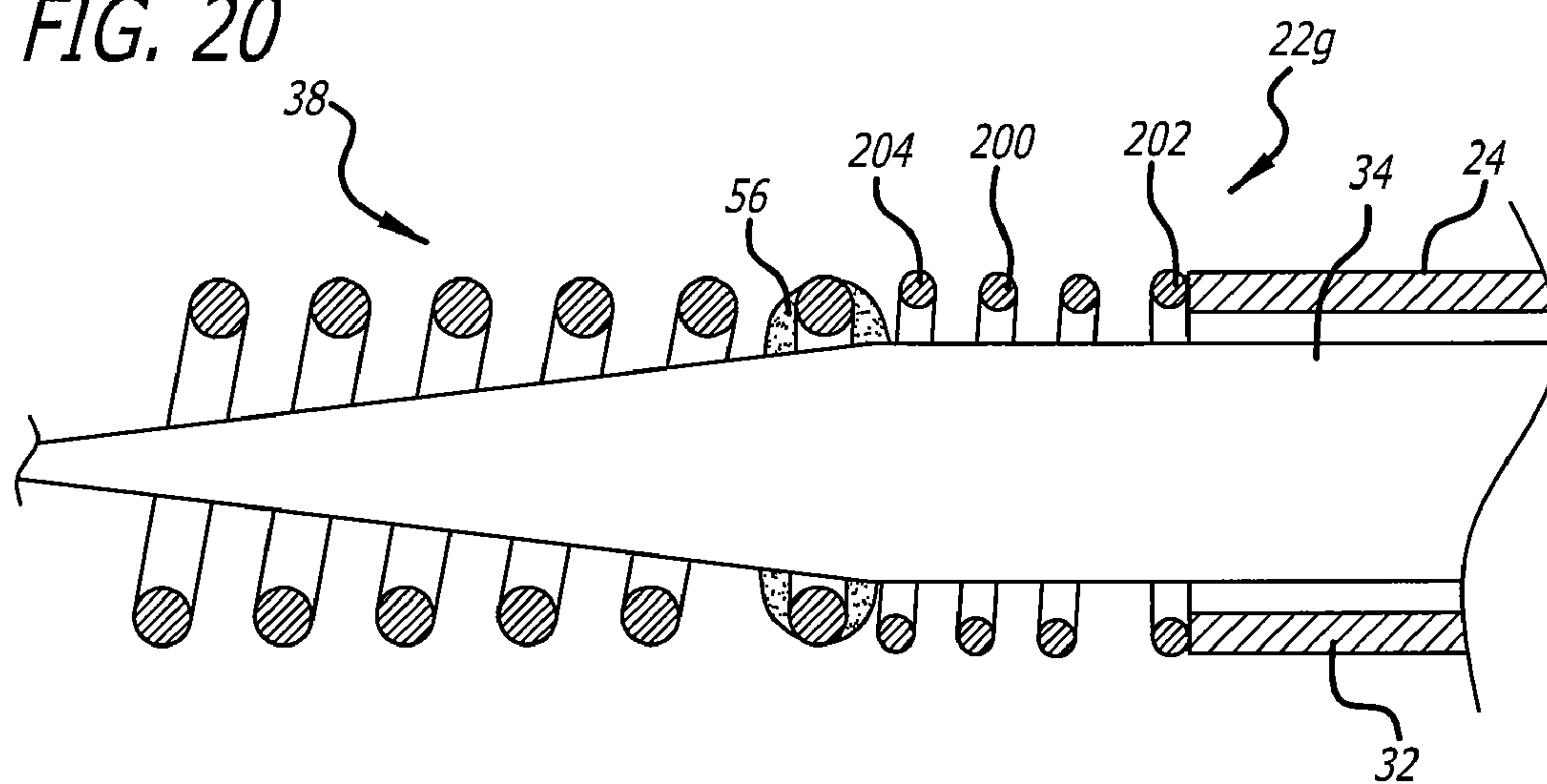


FIG. 21

1

LOCKING COMPONENT FOR AN EMBOLIC FILTER ASSEMBLY

BACKGROUND OF THE INVENTION

The present invention relates generally to medical devices used to perform interventional procedures in a patient's vasculature, which can be delivered through a body lumen via a steerable guide wire and into an area of treatment such as, for example, a stenosed or occluded region of an artery or other body vessel. The present invention is more particularly directed to a locking component disposed on a medical device to allow the medical device to be delivered along the guide wire to the treatment area and locked in place. The locking component of the present invention is intended for use on a standard guide wire of the physician's choice, and does not require a modified guide wire with specially-designed stops or other mechanisms to accomplish the locking function.

Numerous medical procedures have been devised for treating occluded blood vessels to allow blood to flow without obstruction. Such procedures usually involve the percutaneous introduction of an interventional device into the lumen of the artery, usually by a catheter. One widely known and medically accepted procedure is balloon angioplasty in which an inflatable balloon is introduced within the stenosed region of the blood vessel to dilate the occluded vessel. The balloon dilatation catheter is initially inserted into the patient's arterial system and is advanced and manipulated into the area of stenosis in the artery. The balloon is inflated to compress the plaque and press the vessel wall radially outward to increase the diameter of the blood vessel, resulting in increased blood flow. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above described procedure is typical, it is not the only method used in angioplasty.

Another procedure is laser angioplasty which uses a laser to ablate the stenosis by super heating and vaporizing the deposited plaque. Atherectomy is yet another method of treating a stenosed body vessel in which cutting blades are rotated to shave the deposited plaque from the arterial wall. A vacuum catheter is usually used to capture the shaved plaque or thrombus from the blood stream during this procedure.

In the procedures of the kind referenced above, abrupt reclosure may occur or restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the occurrence of reclosure and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside the artery across the lesion. The stent can be crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter.

The above non-surgical interventional procedures, when successful, avoid the necessity of major surgical operations. However, there is one common problem which can become associated with all of these non-surgical procedures, namely, the potential release of embolic debris into the bloodstream that can occlude distal vasculature and cause significant health problems to the patient. For example, during deployment of a stent, it is possible that the metal struts of the stent can cut into the stenosis and create particles of plaque that can travel downstream and lodge somewhere in the patient's vas-

2

cular system. Pieces of plaque material are sometimes generated during a balloon angioplasty procedure and are released into the bloodstream. Additionally, while complete vaporization of plaque is the intended goal during laser angioplasty, sometimes particles are not fully vaporized and enter the bloodstream. Likewise, not all of the emboli created during an atherectomy procedure may be drawn into the vacuum catheter and, as a result, may enter the bloodstream as well.

When any of the above described procedures are performed in the carotid arteries, the release of emboli into the circulatory system can be extremely dangerous and sometimes fatal to the patient. Debris carried by the bloodstream to distal vessels of the brain can cause cerebral vessels to occlude, resulting in a stroke, and in some cases, death. Therefore, although cerebral percutaneous transluminal angioplasty has been performed in the past, the number of procedures performed has been somewhat limited due to the justifiable fear of an embolic stroke occurring should embolic debris enter the bloodstream and block vital downstream blood passages.

Medical devices have been developed to attempt to deal with the problem created when debris or fragments enter the circulatory system following vessel treatment utilizing any one of the above identified procedures. One approach which has been attempted is the cutting of any debris into minute sizes which pose little chance of becoming occluded in major vessels within the patient's vasculature. However, it is often difficult to control the size of the fragments which are formed, and the potential risk of vessel occlusion still exists, making such a procedure in the carotid arteries a high risk proposition.

Other techniques include the use of catheters with a vacuum source which provides temporary suction to remove embolic debris from the bloodstream. However, as mentioned above, there can be complications associated with such systems if the catheter does not remove all of the embolic material from the bloodstream. Also, a powerful suction could cause trauma to the patient's vasculature.

Another technique which has had some success relies on a filter or trap downstream from the treatment site to capture embolic debris before it reaches the smaller blood vessels downstream. The placement of a filter in the patient's vasculature during treatment of the vascular lesion can reduce the presence of the embolic debris in the bloodstream. Such embolic filters are usually delivered in a collapsed position through the patient's vasculature and then expanded to trap the embolic debris. Some of these embolic filters are self-expanding so a restraining sheath is needed to maintain the filter in a collapsed position until it is ready to be deployed within the patient's vasculature. At the target site, the physician can retract the proximal end of the restraining sheath to expose the expandable filter thus allowing the filter to self-expand. Once the procedure is completed, the filter can be collapsed, and the filter with the trapped embolic debris can then be withdrawn from the vessel. While a filter can be effective in capturing embolic material, the filter still needs to be collapsed and removed from the vessel. During this step, there is a possibility that trapped embolic debris can backflow through the inlet opening of the filter and enter the bloodstream as the filtering system is being collapsed and removed from the patient. Therefore, it is important that any captured embolic debris remain trapped within this filter so that particles are not released back into the body vessel.

In order to properly locate and deploy an expandable filter at the target site, some prior art expandable filters vessel are affixed to the distal end of a guide wire or guide wire like member. This allows the filtering device to be steered in the

3

patient's vasculature as the guide wire is positioned by the physician. Once the guide wire is in proper position in the vasculature, the embolic filter can be deployed to capture embolic debris. The guide wire can then be used by the physician to deliver interventional devices such as a balloon angioplasty dilatation catheter or a stent delivery catheter, and to perform the interventional procedure in the area of treatment. After the procedure is completed, a recovery sheath can be delivered over the guide wire using over-the-wire or rapid exchange (RX) techniques to collapse the expanded filter for removal from the patient's vasculature.

Some prior art filtering devices use a filter assembly that separately tracks over the guide wire and attaches to a special fitting or stop located near the distal end of the guide wire. These filtration devices require the stop to be placed near the distal end of the guide wire. The bulk and location of the stop on the guide wire, however, can detrimentally affect the ability of the physician to steer the guide wire and to reach the target area in the patient's vasculature. Depending on its shape and size, the stop formed on the guide wire might cause the guide wire to hang or catch inside a patient's tortuous anatomy, or it might injure the vessel wall. These particular filter systems also require additional manufacturing procedures to properly mount the stop onto the steerable guide wire. Accordingly, the presence of the stop near the distal end of the guide wire may cause unwanted problems during advancement of the guide wire through the patient's vasculature.

Furthermore, many physicians have a preferred brand or type of guide wire that they use during select intravascular procedures. If the filter device requires a specially designed guide wire having a unique fitting or stop to lock to that filter device, then the physician cannot use his or her preferred guide wire due to possible incompatibility between the favored guide wire and the filter device.

Therefore, what is needed is a mechanism for locking a medical device onto a conventional, unmodified guide wire. In particular, there is a need for a filtering system that includes a filter device that is easy to deliver, attaches to a standard guide wire, and eliminates the need for a special fitting or stop formed on the guide wire to help position the filter device. Also, it would be beneficial if the filtering device can be rotatably mounted on the guide wire to prevent the deployed filtering device from rotating while the guide wire is torqued and possibly scraping the vessel wall. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention relates to a medical device, such as an embolic filter assembly, having a locking component that locks the device to a standard guide wire. As such, the locking component can be used in conjunction with conventional, off-the-shelf guide wires, and does not need specially-designed guide wires with fittings or stops to engage the locking component. Furthermore, the locking component of the present invention is capable of being attached to or formed as part of any medical device that needs to be positioned on a guide wire and locked in place.

The locking function of the present invention is intended to selectively immobilize, preferably in one or both directions, the medical device at a predetermined position along the length of the guide wire. Although linear travel may be limited proximally, distally, or both, the medical device may still be free to rotate about the guide wire even when locked to the guide wire.

4

In one embodiment, the embolic protection system includes a guide wire with an elongated core without a stop, a filter assembly having a proximal end and a distal end, and a locking component disposed at one of the ends of the filter assembly. The locking component is adapted to lock onto any point along the guide wire elongated core. Several embodiments of the locking component can be used to lock the filter assembly onto the guide wire, and each of these embodiments is described in detail below.

An embodiment of the locking component used for securing a filter assembly to an elongated wire core includes a frame bushing having a tapered inner diameter that is disposed on the filter assembly. The locking component also includes an interlocking bushing having a first end and a second end, wherein the second end is slidably positioned within the tapered profile, inner diameter of the frame bushing. Both the frame bushing and complementary interlocking bushing are designed to track over the elongated wire core. In this embodiment, filter assembly is secured to the elongated wire core when the second end of the interlocking bushing is pushed into the tapered inner diameter of the frame bushing. A diameter of the second end of the interlocking bushing is decreased from the force applied by the tapered inner diameter when the interlocking bushing is pushed toward and into the frame bushing, thereby causing the second end of the interlocking bushing to grasp or grip the elongated wire core. An optional third bushing, called a crush bushing, may also be used to lock onto the elongated wire core. The third bushing is disposed partially within the interlocking bushing, and as the second end of the interlocking bushing is forced into a smaller diameter, the crush bushing is deformed to constrict onto the elongated wire core.

In another embodiment, an embolic protection system includes a guide wire having an elongated core without stops, and a filter assembly which is disposed on the elongated core for movement therealong. The filter assembly has a first end and a second end, and the locking component in this embodiment is a self-contracting elastic tube disposed on one of the ends of the filter assembly. One end of the elastic tube extends from the filter assembly while a free end of the elastic tube grips down around the wire core to secure the filter assembly thereon. When delivering the filter assembly to the distal end of the guide wire inside a body lumen, a hypotube is used to help move the filter assembly along the wire core. The hypotube is preferably positioned beneath the self-contracting elastic tube to prevent the elastic tube from gripping the guide wire while the filter assembly is traveling along the wire core; as such, the free end of the elastic tube is removably mounted onto the hypotube. By slightly withdrawing the hypotube from underneath, the free end of the elastic tube at least partially self-contracts and locks down onto the wire core.

In yet another embodiment, the locking component or locking device is designed to allow free movement of the filter assembly in one direction and to prevent movement of the filter assembly in the opposite direction. For instance, the locking device is disposed at one end of the filter assembly and allows the filter assembly to move distally toward the treatment site along the guide wire, but locks and prevents the filter assembly from traveling proximally toward the physician. In this embodiment, the locking device includes a thrust bearing. The thrust bearing includes a housing having a tapered interior diametrical profile, and a roller positioned inside the housing that wedges against the guide wire when rolling along the tapered interior diametrical profile of the housing from a greater diameter to a lesser diameter.

In order to control movement in opposite directions, it is possible to have a first locking device disposed at the first end

of the filter assembly and a second locking device disposed at the second end of the filter assembly, where the first locking device prevents movement of the filter assembly in the distal direction and the second locking device prevents movement of the filter assembly in the proximal direction. In order to move the filter assembly along the guide wire distally toward the treatment site, the first locking device is temporarily disabled. To temporarily disable the first locking device, a hypotube engages the roller therein to prevent the roller from moving along the tapered interior diametrical profile and wedging itself against the housing and guide wire. Once the filter assembly is in position, the hypotube is withdrawn. The wedging action is thus enabled, and the first locking device prevents the filter assembly from moving farther distally.

A further embodiment of a locking component or interlocking mechanism includes a housing containing a gripping member that has an expanded state and a contracted state. The interlocking mechanism also includes a cap that engages or screws onto an end of the housing. Once the filter assembly is located at the desired position on the guide wire, the filter assembly is locked-onto the guide wire by tightening the cap onto the housing to transform the gripping member from the expanded state to the contracted state. In one embodiment, the gripping member is a threaded collet, and the cap includes a tapered inner diameter with complementary threads. When the cap is rotationally advanced onto the collet, the action forces the collet into the contracted state thus gripping on to the guide wire.

In another embodiment the gripping member is an o-ring, and the cap having a longitudinal axis, includes an internal surface oriented perpendicularly to the longitudinal axis. As such, when the cap is screwed onto the housing, the action compresses the o-ring into the contracted state to grip the guide wire.

In still another embodiment, an embolic protection system includes a guide wire having an elongated core with a proximal end and a distal end, and a coil disposed at the distal end of the guide wire. A filter assembly has first and second ends and is disposed for travel along the guide wire core, and has a locking component. The locking component is a self-contracting locking coil extending from the filter assembly with a free end. Alternatively, the locking coil may be a discrete structure that is bonded to one of the ends of the filter assembly. The system further includes an optional hypotube disposed over the guide wire, and on which is mounted the locking coil. In use, once the filter assembly is moved to the distal end of the guide wire, the hypotube is at least partially withdrawn from underneath the free end of the locking coil. This allows the free end to contract and grip the tip coil or like structure of the guide wire.

In various other embodiments, the locking component of an embolic protection system includes a variety of shrink tubes. The shrink tube extends from one end of the embolic filter, and both track over a standard guide wire without a stop. At the deployment site, the shrink tube is thermally or chemically actuated so that it shrinks down in diameter to grip the wire core. For this to occur, the shrink tube is preferably made from a shape memory metal or polymer.

If made from a metal, the material may be a nickel-titanium alloy having an austenitic shape set to a smaller diameter while the martensitic shape is deformed to have a larger diameter to facilitate movement along the guide wire. To activate the locking function, heat is introduced to the shrink tube so that the alloy transforms from martensite to its remembered austenitic shape. This causes the shrink down in diameter. Alternatively, the shrink tube may already be in the austenitic phase while in the body lumen, and a hypotube

supporting the shrink tube from underneath prevents the shrink tube from shrinking. The hypotube is withdrawn at the appropriate instance thus allowing the shrink tube to constrict onto the guide wire.

If the shrink tube is made from a polymer instead of a metal, it may be a heat shrinkable type. Such heat shrinkable materials include polytetrafluoroethylene (PTFE), polyvinylchloride (PVC), polyethylene, and the like. Other shape memory polymeric materials can change by a change in acidity, water absorption, and the like. Once at the filter lockdown site, the shrink tube is exposed to heat or similar catalyst.

The present invention further provides a separately deliverable filter assembly having an expandable basket or cage and a filter element. In use, the filter assembly is designed to capture embolic debris created during the performance of a therapeutic interventional procedure or other unwanted particulates entrained in the fluid of a body vessel. The present invention allows the physician to deliver the guide wire of his or her choice with "front line" capabilities to steer through the tortuous anatomy, while still being able to provide filtering protection in the form of a separately deliverable attachment.

It is to be understood that the present invention is not limited by the embodiments described herein. To be sure, the present invention can be used in arteries, veins, and other body vessels. By altering the size of this design, the present invention would be suitable for coronary, peripheral, and neurological applications. Other features and advantages of the present invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view, partially in cross-section, of a guide wire with an embolic filter assembly in the compressed state, and a generic representation of a locking component, all positioned inside a patient's body lumen.

FIG. 2 is a side elevational view of the filter assembly and guide wire locking component of FIG. 1 shown deployed within the body lumen.

FIG. 3 is a side elevational view, partially in cross-section, of a standard guide wire with distal tip coil which can be used with the present invention.

FIG. 4 is a side elevational view, partially in cross-section, of a proximal end of a filter assembly including a locking component in an unlocked position on a guide wire.

FIG. 5 is a side elevational view of the filter assembly of FIG. 4 with the locking component locked onto the guide wire.

FIG. 6 is a side elevational view of the filter assembly of FIGS. 4 and 5 with the locking component locked onto the guide wire, and a clawed hypotube locked onto the locking component.

FIG. 7 is a side elevational view of the filter assembly of FIGS. 4, 5, and 6 with the clawed hypotube attached to the locking component and a recovery sheath advanced over the filter assembly.

FIGS. 8a and 8b are perspective views of embodiments of a claw component that can be connected to the clawed hypotube.

FIG. 9 is a side elevational view, partially in cross-section, of an alternative embodiment of the guide wire locking component including an elastic tube.

FIG. 10 is a side elevational view, partially in cross-section, of another embodiment of the guide wire locking component including two roller clutch assemblies, with one attached to

the proximal end of the filter assembly and the other attached to the distal end of the filter assembly.

FIG. 11 is a side elevational view, partially in cross-section, of the roller clutch assembly attached to the proximal end of the filter assembly of FIG. 10, and showing a hypotube engaging the roller to prevent the roller from locking.

FIG. 12 is a side elevational view, partially in cross-section, of the roller clutch assembly attached to the proximal end of the filter assembly of FIGS. 10 and 11, and showing the hypotube removed and the roller pinching the guide wire.

FIG. 13 is a side elevational view of another embodiment of a locking component attached to the proximal end of a filter assembly.

FIG. 13a is a side elevational view of a shape memory locking tubing attached to the proximal end of the filter assembly.

FIG. 14 is a side elevational view of another embodiment of a locking component attached to the filter assembly.

FIG. 15 is a side elevational view, partially in cross-section, of a collet-type locking component.

FIG. 16 is a side elevational view, partially in cross-section, of a collet-type locking component with an o-ring.

FIG. 17 is a side elevational view of a hand tool for locking the locking component of FIG. 14 attached to the caps of the locking components.

FIG. 18 is a side elevational view, partially in cross-section, of a locking coil in an expanded state positioned overlying a distal tip coil of a guide wire.

FIG. 19 is a side elevational view, partially in cross-section, of the locking coil of FIG. 18, wherein the locking coil has contracted onto the distal tip coil of the guide wire.

FIG. 20 is a side elevational view, partially in cross-section, of a locking coil positioned adjacent a weld bead of a distal tip coil of the guide wire.

FIG. 21 is a side elevational view, partially in cross-section, of the locking coil of FIG. 20, wherein the locking coil has passed over and locked onto the weld bead and the distal tip coil.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to a locking component used to lock a medical device on to a standard guide wire. As such, the locking component does not need to be used with a specially designed guide wire having a complementary "fitting" or "stop" thereon in order to accomplish the locking function. That is, such a standard guide wire has no "fitting" or "stop" defined as any structure formed on the wire or attached thereto before sterilization, whose position relative to the wire is generally stationary or has very restricted linear and/or rotational movement, that is intended to engage a mating locking component of a filtering device or like medical device in order to (a) prevent or limit the movement of that filter device along the guide wire, and/or to (b) assist in the deployment of the filter device.

The above definition of a "fitting" or "stop," however, does not encompass common fixtures found on a guide wire core such as a tip coil, a shaping ribbon, or the like. Further, the definition of "fitting" or "stop" should not encompass what is known in the art as a "step catch." A "step catch" is a stop that is first tracked over the wire so that a mating component can later engage that stop.

For ease of illustration, the following exemplary embodiments are directed to locking components that are attached or disposed on embolic filtering devices, although it is understood that the present invention is applicable for use with

other medical devices that can be delivered in over-the-wire fashion and locked to a standard guide wire. It is contemplated that by altering the size of the components, the present invention can be suitable for coronary, peripheral, and neurological applications. It is understood that the present invention is not limited by the embodiments described herein.

Turning now to the drawings, in which like reference numerals represent like or corresponding elements in the drawings, FIGS. 1 and 2 illustrate an embolic filtering system 20 that includes a guide wire locking component 22; the locking component 22 is generically represented in the drawing. The embolic filtering system 20 is designed to capture, for example, embolic debris which may be created and released into a body lumen during an interventional procedure. The embolic filtering system 20 can also be used to filter any unwanted particles entrained in the fluid of a body lumen such as large microspheres of a therapeutic agent that may be released into the lumen during a localized drug delivery procedure.

The embolic filtering system 20 preferably includes an expandable filter assembly 24 having a self-expanding basket or cage 26 and a filter element 28 attached thereto. The filter assembly 24 has a proximal or first end 30 and a distal or second end 32, and in the embodiment shown in FIG. 1, the locking component 22 is shown disposed at the proximal end 30 of the filter assembly 24. A basket hypotube or coil 33 (and sometimes referred to as an inner housing) is also shown as part of the embolic filtering system 20. The basket hypotube 33 is connected between the proximal and distal ends 30 and 32, and allows the filtering device to be engaged with an elongated (solid or hollow) cylindrical tubular shaft, such as a steerable guide wire 34 having an elongated core 36. The guide wire in the drawings is also shown to have an optional distal tip coil 38. The guide wire 34 has a proximal end section (not shown in FIGS. 1 and 2) that extends outside the patient, and a distal end section 40.

In FIGS. 1 and 2, the embolic filtering system 20 is depicted within an artery 41 or other body lumen of the patient. A portion of the artery 41 has an area that needs treatment, for example, atherosclerotic plaque or stenosis 42 that has built up against the inside wall of the artery 41. To operate the embolic filtering system 20, the physician first inserts the guide wire 34 into the vasculature of the patient, advancing and then positioning the distal end 40 of the guide wire 34 past the area of treatment or lesion. The guide wire 34 is advanced and steered by the physician using techniques well known in the medical profession.

The physician next delivers an interventional device along the guide wire to treat the stenosis 42, or he can first deploy an embolic filtering device past the stenosis 42 to catch possible particles that could break from the stenosis during treatment. If the physician decides to opt for distal embolic protection, a restraining or delivery sheath 44 that delivers the filter assembly 24 separately along the guide wire 34 in a collapsed position can be advanced along the guide wire and downstream from the lesion.

Once the filter assembly 24 is positioned at the distal end section 40 of the guide wire downstream from the lesion, it is locked against the guide wire in place. The expandable filter assembly 24 can then be deployed by the physician by simply retracting the delivery sheath 44 proximally to expose the expandable filter assembly 24. As the restraining sheath 44 is retracted, the self-expanding basket 26 immediately begins to expand within the body lumen 38, causing the filter element 28 to expand as well. By having a locking component 22 that can attach at any point along the elongated core 36 of the guide wire without the use of stops or other mechanisms

specially formed on the guide wire, the physician is able to use a standard, off-the-shelf guide wire of his or her choice.

As shown in FIGS. 1 and 2, the filter assembly 24 may include an obturator 45 made from a soft material such as PEBAX 40D which provides an atraumatic tip to the filter assembly as it is advanced over the guide wire within the patient's vasculature. The soft tipped obturator 45 helps to prevent the distal end of the filter from scraping the walls of the body vessel as it is advanced therethrough. This same type of obturator can be used in accordance with any of the embodiments of the present invention filter assembly with a locking component.

Referring specifically now to FIG. 2, the embolic filtering system 20 is shown in its expanded position within the patient's artery 41. A treatment device (not shown), such as an angioplasty catheter or stent bearing catheter, can be delivered over the guide wire 34 to the area of plaque stenosis for treatment. Any embolic debris created during an interventional procedure released into the bloodstream enters the filter assembly 24 located downstream from the area of treatment. Once the procedure is completed and the embolic debris is collected in the filter element 28, the filter assembly 24 is collapsed by a recovery sheath (not shown) that slides over the filter assembly. The filter assembly 24 is now ready for removal from the patient's vasculature.

As mentioned earlier, the guide wire locking component 22 is preferably used with a conventional guide wire 34. Referring now to FIG. 3, a representation of a conventional guide wire 34 is shown. The guide wire 34 depicted in FIG. 3 includes an elongate core member 36 with a proximal section 48 and a distal section 40. A flexible body member 38 such as a helical tip coil is disposed around the distal section 40, and the helical coil 38 has a proximal end 52 and a distal end 54. In this embodiment, the helical coil 38 has a relatively constant diameter from the proximal end 52 to the distal end 54. The helical coil 36 can be attached to the guide wire 34 at the proximal end 52 by a solder or weld bead 56. Also in this embodiment, the distal end 54 has a rounded solder ball 58. In the event that the spacing between coils is too tight, i.e., the tip is too stiff and does not bend through tortuous anatomy, the physician can simply apply a small amount of proximal force to the coils to cause a portion of the tip coil to expand longitudinally, thus creating space between coil turns.

In general, the standard guide wire used in conjunction with the various embodiments of the present invention locking component does not have a stop, and none is shown in FIG. 3. To be sure, the guide wire can be a standard, off-the-shelf type with some or all of the common structures found on a guide wire, such as tip and intermediate coils, a tapered shoulder, a shaping ribbon, radiopaque markers, coatings of all varieties, solder beads, tip ball, etc. But such a standard guide wire has no "fitting" or "stop" as defined above.

Referring now to FIGS. 4-7, one particular embodiment of a guide wire locking component 22a made in accordance with the present invention is shown exemplifying the various states that the locking component 22a takes when being locked onto a conventional guide wire 34. As shown specifically in FIG. 4, the locking component 22a includes an interlocking bushing 60 having a first end 62 and a second end 64. The interlocking bushing 60 also includes a tapered exterior portion 66 and a central passage 68 extending between the first end 62 and the second end 64. There is also a ring 69 disposed at the second end 64 of the interlocking bushing 60. The locking component 22a further includes a frame bushing 70 having a first end 72 and a second end 74. A central passage 76 runs through frame bushing 70 from the first end 72 to the second end 74, and there is a tapered inner diameter section 78 located at the

first end 72. There is a recess 80 formed on the inner diameter of the frame bushing adjacent to the tapered inner diameter section 78. Another recess 82 is formed on the exterior of the frame bushing 70 near the first end 72. As shown in the drawings, the second end 74 of the frame bushing 70 is attached to the proximal end 30 of the filter assembly 24, through mechanical engagement, chemical bonding, or any other method that is known in the art. In an alternative embodiment, the frame bushing 70 can be formed as part of or integral with the filter assembly 24 structure.

The second end 64 of the interlocking bushing 60 is fitted within the central passage 76 of the frame bushing 70 at the first end 72 and is secured inside the central passage 76 of the frame bushing 70 by a lip 84 formed at an opening on the first end 72 of the frame bushing. In a preferred embodiment, the locking component 22a further includes a crush bushing 86 that is disposed within the central passageways 68 and 76 of both the interlocking bushing 60 and frame bushing 70. As seen in the drawings, the length of the crush bushing 86 preferably extends from near the first end 62 of the interlocking bushing 60 to the recess 80 formed inside the frame bushing 70, although the length may vary.

In use, the embolic filtering system 20 including locking component 22a, is positioned at the distal end section 40 of the pre-deployed guide wire 34 by advancing the delivery sheath 44 and a floating hypotube 88 together distally. As shown in FIG. 4, the floating hypotube 88 is disposed between the guide wire 34 and the delivery sheath 44, wherein a distal end 90 of the floating hypotube abuts the first end 62 of the interlocking bushing 60 and helps move the filter assembly 24 along the guide wire 34. Once the filter assembly 24 is in a desired position along the guide wire 34, the filter assembly 24 can be locked into place by pushing the floating hypotube 88 in a distal direction while the filter assembly 24 is still in a collapsed state inside the delivery sheath 44. As the floating hypotube 88 is pushed distally, the delivery sheath 44 holds the filter assembly 24 in position on the guide wire, and the interlocking bushing 60 is pushed toward and into the frame bushing 70. The second end 64 of the interlocking bushing 60 is pushed along the tapered inner diameter section 78 of the frame bushing 70, and as the inner diameter along the tapered inner diameter section 78 narrows, the outer diameter of the second end 64 of the interlocking bushing also narrows, thereby deforming the crush bushing 86 and securing the filter assembly 24 onto the guide wire 34. In an embodiment not including the crush bushing 86, the second end 64 of the interlocking bushing would narrow to a small enough diameter to grip the guide wire and to secure the filter assembly onto the guide wire.

Referring to FIG. 5, the interlocking bushing 60 is shown snapped together with the frame bushing 70 and the crush bushing 86 gripping the guide wire. When the interlocking bushing 60 is snapped together with the frame bushing 70, they are locked together because the ring 69 is held inside the recess 80 of the frame bushing. Once the filter assembly 24 is secured to the guide wire 34, the delivery sheath is removed to allow the filter element 28 to deploy within the lumen. The floating hypotube 88 is also removed from the body lumen using conventional, over-the-wire techniques or in a rapid exchange manner if the hypotube has an open slit spanning its length.

When the intravascular procedure is completed, a recovery sheath 92, as shown in FIGS. 6 and 7, is used to collapse and remove the filter assembly 24 from the body lumen. To ensure that the filter assembly 24 does not slide distally when the recovery sheath 92 is advanced over the filter assembly, an optional clawed hypotube 94 having a clawed end 96 may be

11

used to lock on to the locking component **22a**. The clawed hypotube **94** is advanced along the guide wire **34** until the clawed end **96** reaches the first end **62** of the interlocking bushing **60**. At this point the clawed hypotube **94** is further advanced, riding up the tapered exterior portion **66** of the interlocking bushing **60** and then locking into the recess **82** formed on the exterior of the frame bushing **70** as shown in FIG. 7. A physician would hold the clawed hypotube **94** in place while collapsing the filter assembly **24** with the recovery sheath **92**. Once the filter assembly is retracted into the recovery sheath, the guide wire, clawed hypotube, and recovery sheath encapsulating the filter assembly are simultaneously removed from the body lumen.

In another embodiment shown in FIGS. **8a** and **8b**, the clawed end of the clawed hypotube can be made as an additional claw component **98** having legs **100** that is connected in some way to or extends from the clawed hypotube. The additional claw component **98** can vary in the number of legs, leg shape, thickness and length to minimize the locking force. FIG. **8a** shows one embodiment where the claw component **98** has three legs **100**, and FIG. **8b** shows an embodiment where the claw component **98** has four legs.

Yet another embodiment of a locking component is shown in FIG. **9**, and is designated **22b**. The locking component **22b** includes a bushing **102** with a central passageway **103** and a self-contracting elastic tube **104** having a free end **105** for gripping the guide wire **34**. The elastic tube **104** can be made preferably from any elastomer or elastic polymer. The bushing **102** shown in FIG. **9** resembles the structure of the interlocking bushing **60** and frame bushing **70** when snapped together, and includes a first end **106**, a second end **108**, a tapered exterior portion **110** on the first end, and a recess **112** that is located adjacent to the tapered exterior portion. Also included in this locking component **22b** is an inner housing tube **114** that is disposed within the central passageway **103** of the bushing **102**, and the inner housing tube has a connecting end **116** that extends proximally outward from the first end **106** of the bushing **102**. Although not shown in the drawings, the inner housing tube **114** may extend to the distal end **32** of the filter assembly **24**. In other embodiments, the inner housing tube **114** can be a coil.

In this embodiment, the second end **108** of the bushing **102** is optionally bonded to the proximal end **30** of the filter assembly **24** and to the outer diameter of the inner housing tube **114**. There is also an optional bond between the outer diameter of the connecting end **116** of the inner housing tube **114** and the inner diameter of a portion of the elastic tube **104**. Of course, these structures may alternatively be formed as one piece with the filter assembly **24**.

To prevent the free end **105** of the elastic tube **104** from contracting and gripping onto the guide wire **34** during delivery of the filter assembly **24** to the distal end section **40** of the guide wire, a floating hypotube **118** is positioned underneath the elastic tube **104** and abuts the connecting end **116** of the inner housing tube **114**. The free end **105** of the elastic tube **104** is stretched to fit over the floating hypotube **118**. There may be a lubricious coating on the contacting surfaces of housing tube **114** and floating hypotube **118** to minimize friction. This design allows the floating hypotube **118** to push directly against the inner housing tube **114** for basket deployment.

Once the filter assembly **24** including the locking component **22b** is positioned at the distal end section **40** of the guide wire, the floating hypotube **118** is translated proximally while the delivery sheath **44** is held stationary. The hypotube **118** optionally has a length sufficient long for the physician to access and move it from its proximal end; a linkage of some

12

type can be used for this purpose too. The movement of the floating hypotube **118** relative to the elastic tube **104** at least partially dismounts the free end **105** of the elastic tube **104** from the floating hypotube **118**. When dismounted from the floating hypotube **118**, the free end **105** of the elastic tube **104** constricts and grips onto the guide wire **34** to secure the filter assembly **24** thereon. This embodiment of the filter assembly **24** shown in FIG. **9** can be removed from the body lumen in a similar manner as the embodiment having locking component **22a** shown in FIGS. **6** and **7** by using the clawed hypotube **94** to lock into the recess **112** of the bushing **102**.

Although a particular embodiment is shown in FIG. **9**, it is contemplated that the locking component **22b** could include only the elastic tube **104** without the bushing **102**, and the inner housing tube **114** could be attached only to the proximal end of the filter assembly **24**. Also, it is contemplated that the elastic tube **104** can be attached directly to or formed as part of the proximal end of the filter assembly **24** without the need for the inner housing tube **114** on the bushing **102**. One advantage of using the elastic tube **104** is that it can withstand high axial forces that may be encountered during delivery of the filter assembly **24**.

Another embodiment of the present invention is illustrated in FIGS. **10-12**. This embodiment also allows a filter assembly **24** to be positioned and locked on a pre-deployed, standard guide wire **34** that does not include any stops. Referring to FIG. **10**, the embolic filtering system **20** is shown on a guide wire optionally having two locking components or devices **22c** attached to or formed as part of both the proximal end **30** and the distal end **32** of the filter assembly **24**. The locking device **22c** allows free movement of the filter assembly in one direction and prevents movement of the filter assembly in the opposite direction. The locking device **22c** on the proximal end **30** of the filter assembly in FIG. **10** prevents movement in the distal direction while the locking device **22c** on the distal end **32** of the filter assembly is attached to prevent movement in the proximal direction, thereby positionally affixing the filter assembly along the length of the guide wire.

The locking device **22c** of this embodiment is a thrust bearing. The thrust bearing includes a housing **120** having a first end **122** and a second end **124**, with a tapered profile interior diametrical section **126** adjacent to the first end and a flat profile interior diametrical section **128** adjacent to the second end. Located within the housing **120** is a roller **130** that wedges against the guide wire when the roller rolls along the tapered interior diameter of the housing from a greater diameter to a lesser diameter. The roller **130** in this embodiment includes a thrust plate **132** that holds a loose set of ball, pin, or needle bearings **134** in a circular arrangement. An optional spring **136** is positioned inside the housing **120** within the flat interior diameter section **128** and one end of the spring is pressed against the thrust plate **132** to bias the roller tightly against the tapered interior diametrical section **126**. The housing **120** is hollow with openings at both ends to allow the guide wire to pass through.

When the guide wire **34** is moved in the direction away from the ramp or tapered interior section **126**, the guide wire passes with little resistance. On the other hand, when the guide wire **34** is moved in the direction of the tapered interior section **126**, the biasing force from the spring **136** urges the roller **130** onto the tapered interior section. The smaller space of the tapered interior section forces the ball bearings closer together and reduces the inside diameter of the roller thereby wedging or pinching the roller down onto the guide wire. Accordingly, this roller clutch mechanism is self-actualizing and relies on a wedging principle of operation.

13

In FIG. 10, the second end 124 of the housing 120 is attached to or extends from the proximal end 30 of the filter assembly 24, and on the distal end 32 of the filter assembly, the second end 124 of another housing 120 is attached or extends therefrom. The locking component 22c at the ends of the filter assembly 24 are mirror images of one another. Since the locking component 22c on the proximal end 30 of the filter assembly 24 prevents movement distally, the locking component needs to be disabled while the filter assembly travels along the guide wire toward the distal end section 40. To accomplish this, an optional floating hypotube 138 (shown in FIG. 11) tracks over the guide wire 34 and is situated against the locking component 22c at an opening at the first end 122 of the housing 120. The floating hypotube 138 is attached to or is formed from the proximal end 30 of the filter assembly 24.

Referring again to FIG. 11, during delivery of the filter assembly, a distal end 140 of the floating hypotube 138 is positioned against the thrust plate 132 to keep the roller 130 off of the tapered interior section thereby preventing the wedging action. The filter assembly can then be delivered to the treatment area in a similar manner as previously discussed, with the exception that a floating hypotube 138 is used to disable the locking component 22c on the proximal end 30 of the filter assembly to enable free movement distally. Once the filter assembly 24 is in position on the guide wire 34, the floating hypotube 138 disengages from the housing 120, as shown in FIG. 12, to prevent further distal movement of the filter assembly. As shown in the drawing, the locking component 22c at the distal end 32 of the filter assembly is already activated to prevent proximal movement. Consequently, the filter assembly 24 is secured in both directions on the guide wire.

FIG. 12 shows the roller 130 clamping down on the guide wire 34, preventing distal movement. The delivery sheath can then be withdrawn to allow the filter element to expand in the body lumen. When the procedure is complete, a delivery sheath is used to collapse the expanded filter assembly and to remove the filter assembly along with the guide wire from the body lumen.

Another embodiment of a locking component is shown in FIG. 13, in which shape memory is used to lock a filter assembly onto the elongated core of any guide wire with no special features such as stops to accomplish the locking function. The locking component in this embodiment is labeled 22d, and is a shape memory tubing 150 that can be attached to or formed at the proximal end 30 or the distal end 32 of the filter assembly 24. It is contemplated that one shape memory tubing 150 can be disposed at the proximal end 30, and another shape memory tubing can be disposed at the distal end 32. As shown in FIG. 13, the filter assembly 24 can have a rotatable ferrule or bushing 152 disposed at one or both of its ends to allow free rotation of the basket or filter assembly on the guide wire, and with this design, the shape memory tubing 150 can be attached to or formed as part of the ferrule or bushing.

The shape memory tubing 150 includes a tubular body 154 having a first end 156 and a second end 158. The tubular body 154 is slidably positioned along the elongated core of a guide wire, and the first end 156 is attached to or formed from the filter assembly that is to be locked to the elongated core. The second end 158 grips the elongated core when the tubular body is transformed from an expanded state to a contracted state. In an expanded state or non-contracted shape, the inside diameter of the tubular body 154 is larger than the outside diameter of the guide wire, and the tubular body 154 can be moved along the guide wire until the filter assembly is at a

14

desired target site. At this moment, the shape memory tubing 150 transforms into the contracted state, thereby decreasing its inside diameter so that the shape memory tubing grips onto the elongated core.

In one embodiment, the shape memory tubing 150 can be made of a shape memory polymeric material such as a heat shrinkable polymeric tubing section. The tubing has an inside diameter slightly larger than the largest outside diameter of the guide wire 34 so that the filter assembly can freely traverse along the length of the guide wire. Once the filter assembly is at the desired location, the shape memory tubing is heat shrunk to its contracted state to grip onto the guide wire. The heat shrink tubing can be contracted down to grip on to the wire core, or on to any conventional structure found on a standard guide wire, such as a tip or intermediate coil, a solder bead, or the like.

To activate the polymeric heat shrink tubing material, an infrared radiation source such as a laser or focused lamp, a sterile heat gun, an injection of heated saline, or any other source of heat known in the art may be used; known methods of cross-linking thermoplastic polymer tubing may likewise be used. Indeed, all heat shrinkable, biocompatible, polymeric tubing known in the art can be used, and preferably include polynorbornene, polytetrafluoroethylene ("PTFE"), polyethylene, polyurethane, or polyvinyl chloride ("PVC").

Other shape memory polymeric materials can also be used to form the shape memory tubing 150. For example, shape memory polymers whose shape memory is triggered by means of pH or acidity change in the ambient fluid, or liquid absorption, are contemplated. Such polymeric materials can be found in, for example, U.S. Pat. No. 5,163,952 (Froix) whose contents are hereby incorporated by reference.

The shape memory tubing 150 may also include a two-component shape memory polymer, with one component being a "hard," high glass temperature polymer for setting the original shape, and the other complementary component being a "switch" low glass temperature polymer for changing the shape. These shape memory polymers can be returned to a remembered state using a number of stimuli including heat or UV light.

When applying shape memory polymers to a locking component, the filter assembly is preferably first secured onto the distal end of the guide wire while outside of the patient's body. As a result, use of these shape memory polymers as locking components can quickly transform any standard guide wire without a stop into a guide wire with an appended embolic filter. Once the filter assembly is attached to the physician's choice of guide wires, the modified guide wire with the filter assembly collapsed by a delivery sheath is inserted into and positioned within the body lumen of the patient.

In another embodiment, the shape memory tubing 150 is preferably made from a shape memory metal such as nickel-titanium ("nitinol"). FIG. 13a shows the metallic shape memory tubing 150 disposed at one end of a filter assembly. As seen in the drawing, the tubing 150 may have laser cut openings to create a strut pattern as in a stent. Strut patterns with openings having a variety of geometric shapes, sizes, and arrangements are contemplated. Although nickel-titanium is the preferred shape memory alloy to use for the shape memory tubing 150, other shape memory alloys known in the art can be used as well, including copper-aluminum-nickel, copper-zinc-aluminum, and iron-manganese-silicon alloys. Nickel-titanium with the addition of a ternary element can also be used.

The locking component embodied in the nickel-titanium shape memory alloy tubing can be attached to the guide wire

15

before or during the medical procedure on a pre-deployed guide wire. To attach the locking component on a guide wire prior to the medical procedure, the nickel-titanium shape memory alloy tubing is heated from a low temperature, martensitic phase to a high temperature, austenitic phase, which austenitic phase recovers the remembered shape. Generally speaking, a transition temperature (usually designated M_s , M_f , A_s , or A_f) separates one phase from the other, and in one embodiment, the transition temperature is set at about 37 degrees C., or human body temperature, or just below that temperature. When the nickel-titanium alloy is heated to above the transformation temperature, the tubing reverts to its austenitic, remembered shape. If the remembered shape is heat set to have a small diameter, reversion of the tubing to this small diameter remembered shape contracts the tubing onto the guide wire.

While below the transition temperature in the martensitic phase, the locking component with filter assembly attached is deformed to a larger diameter to fit on to the distal end of the guide wire. The locking component is then heated to above the transition temperature. It now transitions into the austenitic phase shrinking down in diameter to lock on to the guide wire. The guide wire can thus be modified to add a filter assembly to the distal tip while outside the patient's body prior to the procedure. A delivery sheath, used to collapse the self-expanding filter assembly would, of course, be needed prior to insertion in a patient.

The above principle can be applied to the shape memory tubing while inside the body. First, the shape memory tubing is joined to or is formed from one end of the filter assembly as shown in FIG. 13a. The tubing 150 is in its low temperature, martensitic phase with a large diameter to enable movement along the guide wire. Second, the filter assembly is delivered to the target site, tracking along the guide wire in a delivery sheath while the nickel-titanium shape memory tubing is thermally isolated to remain in the martensitic phase and in an expanded state until the delivery sheath is removed to deploy the filter assembly. Third, once exposed to the warmer ambient environment, the nickel-titanium shape memory tubing 150 reaches or exceeds the transition temperature at which moment the tubing 150 returns to its austenitic, remembered shape. The smaller diameter of the remembered shape contracts and clamps the tubing 150 onto the guide wire 34. The filter assembly is thus locked in place on the guide wire.

In an alternative embodiment (not shown), a hypotube is slidably disposed over the guide wire and located underneath the shape memory tubing 150. The tendency of the nickel-titanium alloy when exposed to high temperatures to revert back to its small diameter remembered shape is resisted by the fixed diameter hypotube underneath. When situated on the hypotube, the alloy is in its stress-induced martensitic (SIM) phase. Once at the target site, the hypotube is withdrawn through conventional methods thus allowing the now unsupported shape memory tubing to self-contract onto the guide wire. In the self-contraction, the alloy generally transforms from SIM to the austenitic phase. This embodiment may be more accurately characterized as applying pseudoelasticity or superelasticity of the alloy rather than the shape memory effect, because when the support or stress is removed causes the phase change, and that phase change occurs isothermally. Also, an optional lubricious coating may be added to the hypotube exterior to ease dismount of the shape memory tubing 150 from the hypotube.

The recovery or transition temperature of the nickel-titanium alloy may be altered by making minor variations in the composition of the metal and in processing the material. In developing the correct composition, biological temperature

16

compatibility must be determined in order to select the correct transition temperature. In other words, when the nitinol metal is heated, it must not be so hot that it is incompatible with the surrounding body tissue.

Other shape memory materials may also be used, such as, but not limited to, irradiated memory polymers such as autocrosslinkable high density polyethylene (HDPEX). Shape memory alloys are known in the art and are discussed in, for example, "Shape Memory Alloys," Scientific American, Vol. 281, pp. 74-82 (November 1979), whose contents are incorporated herein by reference.

Referring now to FIGS. 14-17, another embodiment of a locking component 22e is shown, with one locking component attached to each end of the filter assembly 24. The locking component 22e or interlocking mechanism can be attached to at least one of the ends of the filter assembly and includes a housing 160 and a gripping member 162 inside the housing having an expanded state and a contracted state, and a cap 164 that engages the housing. By engaging the cap 164 with the housing 160, the gripping member 162 is transformed from the expanded state to the contracted state thereby locking the filter assembly 24 to the guide wire.

As seen in FIG. 15, the gripping member 162 in this embodiment refers to a collet mechanism 166. The collet mechanism 166 features a cap 164 with a tapered inside diameter 168 that engages fingers, claws, projections, or a notched lip extending from the housing 160. As the cap 164 is advanced over external threads 170, the fingers, claws, projections, or notched lip is forced to slide along the ever-decreasing inside diameter of the cap 164. As a result, the fingers, claws, projections, or notched lip is forced radially inward to clamp down on the guide wire.

In another embodiment shown in FIG. 16, the gripping member 162 is a pliable o-ring 174 preferably made of an elastomer or soft polymer. The o-ring 174 as the name implies has a donut hole in the center, and is seated at one end within the guide wire lumen of the tubular housing 160. If the o-ring 174 is compressed to reduce its volume, the o-ring will correspondingly expand in a direction that is unrestricted to maintain that volume. A cap 164 has a compression surface 176 for engaging the o-ring 174. When a cap 164 having internal threads 172 is advanced over external threads 170 of the housing 160, the compression surface 176 engages and compresses the o-ring against the back side of the lumen, and the inside diameter of the guide wire lumen restricts expansion of the o-ring radially outward.

Because it is restricted from expansion in all other directions, to maintain its volume under this compression, the only unrestricted direction is radially inward to close down the donut hole. Thus, advancing the cap 164 compresses the o-ring which in turn closes down the donut hole thereby clamping down on a guide wire passing therethrough.

FIG. 17 shows an optional tool 178 having a first gripping end 180, a second gripping end 182, and a handle 184. The tool 178 can be used to grip the caps 164 on each of the locking components 22e found on both ends of the filter assembly 24 to screw the caps onto the housings. To operate, the filter assembly 24 including the locking components 22e is tracked over the guide wire 34 to a desired location.

Once at the desired location on the guide wire 34, the ends 180 and 182 of the tool 178 are fitted over the caps 164, which are loosely attached to the housing 160. The physician can then turn the tool 178 in one direction using the handle 184 to tighten the caps 164. Only one direction is needed to tighten both caps at once by having a left-hand thread on the locking component 22e at the proximal end 30 of the filter assembly 24 and a right-hand thread on the locking component at the

17

distal end **32** of the filter assembly. By tightening the cap **164** onto the housing **160**, the gripping member **162** is forced into its contracted state to grip onto the guide wire **34**. Any standard guide wire can be transformed into a filter guide wire by attaching a filter assembly having the locking component **22e** attached at one or both of its ends.

Referring now to FIGS. **18** and **19**, a locking component is shown that can attach to any pre-deployed guide wire having a conventional distal tip and/or intermediate coil. In this embodiment, a locking component **22f** is a self-contracting locking coil **190** having an attached end **192** and a free end **194**, with the attached end secured to or formed as part of the distal end **32** of the filter assembly **24**. The locking coil **190** is preferably made from nitinol, although other biocompatible materials may be used.

As seen in FIG. **18**, an optional hypotube **196**, preferably a thin-walled, lased hypotube, is positioned underneath the locking coil **190** and supports the free end **194** of the locking component **22f** thereon. The hypotube **196** is located coaxially in between the guide wire and the filter assembly **24**, and keeps the coil **190** in an expanded state while the filter assembly is moved along the guide wire to the distal end section **40**. Once the hypotube **196** is at least partially or entirely withdrawn, the support for the locking coil **190** is partially or totally eliminated. As a result, the free end **194** of the coil **190** contracts around, on top of, and/or in between the turns of the distal tip and/or intermediate coils **38**.

This embodiment only requires that the guide wire have a conventional coil **38** disposed thereon, and does not require the guide wire to have any special features, such as a stop, to facilitate locking the filter assembly thereto. In this embodiment of the invention, the elongated guide wire core has no stops thereon. Further, the tip/intermediate coils **38** and locking coil **190** can have any pitch and any number of turns. The number of turns and pitches of the coils **38**, **190** may be different as shown or may be the same. The wire diameters of the coils **38**, **190** may be different as shown or the same. Regarding the compliance or stiffness of the coils **38**, **190**, this characteristic can be selected as necessary to maximize guide wire performance so long as there is enough stiffness to interlock the coils and minimize inadvertent detachment of or slippage between the coils **38**, **190**.

Preferably, the locking coil **190** has a smaller diameter than the tip/intermediate coils **38** to favor the interlacing action where the smaller diameter wires easily slip in between the turns of the larger tip/intermediate coils **38**. Also, it is preferable to have different pitches between the locking coil **190** and the tip/intermediate coils **38** to improve contact and make for a better lock between the parts.

The locking component **22f** described above can be used to attach an embolic protection device to a guide wire to capture embolic debris released into a blood vessel of a patient. A guide wire **34** having an elongated core **36** with proximal and distal ends and a coil **38** disposed at the distal end of the guide wire is inserted into a blood vessel and advanced to a treatment area. The filter assembly **24** is then slidably mounted onto the guide wire and advanced along with the hypotube **196** that is positioned between the guide wire and the filter assembly and which radially supports the self-contracting locking coil **190** in an expanded state.

The filter assembly **24**, being collapsed by a delivery sheath, and the hypotube **196** are then directed to the distal end section of the guide wire which should be positioned downstream from the treatment area. Once the locking coil **190** extending from the distal end **32** of the filter assembly **24** is positioned at least partially over one of the tip coils **38** of the guide wire, the hypotube **196** is withdrawn proximally out of

18

the body lumen, thereby allowing the free end **194** of the coil **190** to contract around the tip coil. This locks the filter assembly to the guide wire as shown in FIG. **19**. The delivery sheath is then removed to allow the filter element to expand inside the body lumen.

A similar embodiment is shown in FIGS. **20** and **21**, where a locking component **22g** is a self-contracting locking coil **200** that is attached to or extends from the distal end **32** of the filter assembly **24** and has an attached end **202** and a securing end **204**. The locking coil **200** has an inside diameter that is slightly larger than outside diameter of the elongated core of the guide wire, but slightly less than the outside diameter of a proximal solder or weld bead **206** that joins the distal tip coil **28** to the guide wire core. In this embodiment, the locking coil **200** slides up and over a bump or taper created by the solder or weld bead **56**, which is one example of a protrusion, and locks into the distal tip coils **38** as shown in FIG. **21**. As seen in FIG. **21**, the locking coil at least partially overlies the distal coil such that turns of the locking coils and the distal coil interlace and engage with one another to lock the distal coil to the locking coil. Once the locking coil **200** is locked into the distal tip coil or coils **38**, the delivery sheath can be removed to expand the filter element.

It is also possible for the locking coil **200** to be pushed over a solder that is attaching an intermediate coil to the guide wire and locked onto the intermediate coil. Hence, the locking coil **200** can be locked onto the turns of the distal coil or coils, the weld or solder bead, or both. In sum, this embodiment may be used on any guide wire having a conventional coil that is welded or soldered to the core, and no special feature such as a stop is needed to lock the locking component to the wire core.

The dimensions and specifications of each of the locking components described above can be varied to meet almost any design criteria. For coronary and other procedures which typically use about a 0.014 inch diameter guide wire, the maximum coil outer diameter should be about 0.0138 inch. The proximal guide wire core would be about 0.012 inch or the maximum diameter that would fit into the tapered opening. It should be appreciated that modifications can be made to the guide wire, filter assembly and guide wire locking component without departing from the spirit and scope of the present invention.

The elongated core which forms part of the guide wire is typically comprised of metal, preferably stainless steel or a nickel-titanium alloy or a combination thereof, but can also consist of any material that yields the approximate mechanical properties of the named metals so long as the material is sufficiently biocompatible. Other materials such as high strength alloys may also be used for the core, either alone, or in combination with other materials such as those previously mentioned. The proximal section of the core and any portion of the core not covered by the flexible body or coil may optionally be used with a lubricious coating such as a fluoropolymer, e.g., TEFLON® by DuPont. It may also be coated with a silicone based coating, such as MICRO-GLIDE® coating used by the present assignee, Advanced Cardiovascular Systems, Inc. on many of its commercially available guide wires. Other similar coatings, for example, hydrophyllic coatings, or a combination of any of the above-mentioned coatings may also be used.

The flexible body or coil **38** can be disposed around all or part of the guide wire **34**. The flexible body can be comprised of many suitable materials that allow for increasing the diameter of the guide wire in the distal section without adding substantial stiffness to that section. Suitable materials include polymers, composites, and metals. Preferably the flexible

body is comprised of a helical shaped metallic coil, more preferably a metal or composition of metal or alloys with some degree of radiopacity in order to facilitate fluoroscopic viewing of the device while in use. Metals suitable for the flexible body may include gold, platinum, tantalum, stainless steel, and nickel-titanium alloys, MP35N, or a combination or alloy of any of the foregoing. A flexible body comprised of metallic helical coils is typically comprised of coil winding material that can have a cross-sectional diameter of about 0.001 inch (0.025 mm) to about 0.008 inch (0.20 mm), preferably about 0.002 inch (0.05 mm) to about 0.004 inch (0.1 mm).

The expandable basket of the filter assembly can be made in many ways. One particular method of making the basket is to cut a tubular member, such as nickel-titanium hypotube, to remove portions of the tubing in the desired pattern for each strut, leaving relatively untouched the portions of the tubing which form the structure. The tubing may be cut into the desired pattern by means of a numerical or computer controlled laser. The tubing used to make the basket can be made of suitable biocompatible material, such as spring steel. Elgiloy is another material which could possibly be used to manufacture the basket. Also, very elastic polymers could be used to manufacture the basket.

The strut size is often very small, so the tubing from which the basket is made may have a small diameter. Typically, the tubing has an outer diameter on the order of about 0.020-0.040 inch in the unexpanded condition. Also, the basket can be cut from large diameter tubing. Fittings are attached to both ends of the laser cut tube to form the final basket geometry. The wall thickness of the tubing is usually about 0.076 mm (0.001-0.010 inch). As can be appreciated, the strut width and/or depth at the bending points are less. For baskets deployed in a body lumen, such as with PTA applications, the dimensions of the tubing may be correspondingly larger. While it is preferred that the basket be made from laser cut tubing, those skilled in the art realize that the basket can be laser cut from a flat sheet and then rolled up in a tubular configuration with the longitudinal seam welded.

Generally, the tubing is put in a rotatable collet fixture of a machine controlled mandrel for positioning the tubing relative to a laser. According to machine encoded instructions, the tubing is rotated and moved longitudinally relative to the laser, which is also machine controlled. The laser selectively removes the material from the tubing by ablation and a pattern of openings is cut into the tube. The basket can thus be laser cut much like a stent is laser cut. Details on how the tubing can be cut by a laser are found, for example, in U.S. Pat. Nos. 5,759,192 (Saunders), 5,780,807 (Saunders), and 6,131,266 (Saunders), whose contents are hereby incorporated by reference.

The polymeric material which can be used to create the filter element include, but is not limited to, polyurethane and Gortex, both commercially available materials. Other possible suitable materials include ePTFE. The material can be elastic or inelastic. The wall thickness of the filter element is preferably about 0.00050-0.0050 inch. The wall thickness may vary depending on the particular material selected. The material can be shaped into a cone or similar shape using blow mold technology or dip molding technology.

Perfusion openings in the filter element can be any number of shapes or sizes. A laser, a heated rod, or other methods can be used to create to perfusion openings in the filter material. The openings would, of course, be properly sized to prevent passage of the embolic debris. The perfusion openings can be laser cut preferably into a spiral pattern or some similar pattern that aids in the re-wrapping of the filter media during closure

of the device. Additionally, the filter material can have a "set" put in it much like the "set" used in dilatation balloons to make the filter element re-wrap more easily when transitioning into the collapsed state.

The restraining sheath can be made from a polymeric material such as cross-linked HDPE. The sheath can alternatively be made from a material such as polyolefin, which has sufficient strength to hold the compressed filter assembly, and which has a relatively low coefficient of friction to minimize any drag between the filter assembly and the sheath. Friction can be further reduced by applying a coat of silicone lubricant, such as MICROGLIDE®, to the inside surface of the restraining sheath before the sheath is placed over the filter assembly. Silicone also can be placed on the filter material as well.

Further modifications and improvements can be made to the devices and methods disclosed herein without departing from the scope of the present invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

We claim:

1. An embolic protection device that locks to any point along a guide wire, comprising:

an elongated guide wire core, the core having a proximal end and a distal end;

a first guide wire coil, the first guide wire coil having a proximal end and a distal end, wherein the first guide wire coil is constructed of a plurality of turns of wire radially disposed about the distal guide wire core, and the proximal end of the guide wire coil is affixed to the guide wire core adjacent to the distal end of the guide wire core;

a filter assembly having a proximal end and a distal end, disposed on the guide wire core; and

a second guide wire coil, the second guide wire coil having a proximal end and a distal end, wherein the second guide wire coil is constructed of a plurality of turns of wire, and the proximal end of the second guide wire coil is coupled to the distal end of the filter assembly, wherein the second guide wire coil is configured to overlay the first guide wire coil such that turns of the second guide wire coil interlace with turns from the first guide wire coil to lock the second guide wire coil to the first guide wire coil.

2. The embolic protection device of claim 1, wherein at least one of the turns of the second guide wire coil includes a heat shrinkable shape memory metal alloy.

3. The embolic protection device of claim 1, wherein the embolic protection device includes a guide wire locking component that includes at least one of a threaded engagement and a frictional engagement.

4. The embolic protection device of claim 1, wherein the embolic protection device includes a guide wire locking component that includes wire locking component includes a thrust bearing.

5. The embolic protection device of claim 1, wherein the embolic protection device includes a guide wire locking component that includes wire locking component includes a heat shrinkable shape memory polymer.

6. An embolic protection system for use in a patient, comprising:

a guide wire having a core without stops;

a filter assembly having a first end and a second end; and

a locking component disposed on at least one of the ends of the filter assembly, the locking component having an expanded state and a contracted state;

21

wherein the locking component locks on the guide wire core when the locking component is transformed from the expanded state to the contracted state; and
the guide wire core includes a distal coil, and the locking component includes a locking coil at least partially over-
lying the distal coil such that turns of the locking coil and the distal coil interlace and engage.

7. The embolic protection system of claim 6, wherein the locking component includes a shape memory polymer.

8. The embolic protection system of claim 7, wherein the locking component includes a high glass temperature polymer and a low glass temperature polymer.

22

9. The embolic protection system of claim 6, wherein the locking component includes a heat shrink polymer.

10. The embolic protection system of claim 6, wherein the locking component includes a shrinkable polymer triggered by acidity change.

11. The embolic protection system of claim 6, wherein the locking component includes a shape memory nickel-titanium alloy having an austenitic contracted state and a martensitic expanded state.

12. The embolic protection system of claim 11, wherein a transition temperature of the shape memory nickel-titanium alloy is set to about body temperature of the patient.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,678,129 B1
APPLICATION NO. : 10/805455
DATED : March 16, 2010
INVENTOR(S) : Douglas H. Gesswein et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, (75), Inventors, delete "Robert C. Hazelden" insert instead --Robert C. Hayzelden--.

Signed and Sealed this
Fifth Day of April, 2011

A handwritten signature in black ink, reading "David J. Kappos". The signature is written in a cursive, flowing style with a large initial "D" and a stylized "K".

David J. Kappos
Director of the United States Patent and Trademark Office